PUBLIC HEALTH RESOURCE NETWORK



Legal Obligations of District Health System



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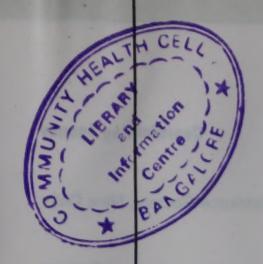
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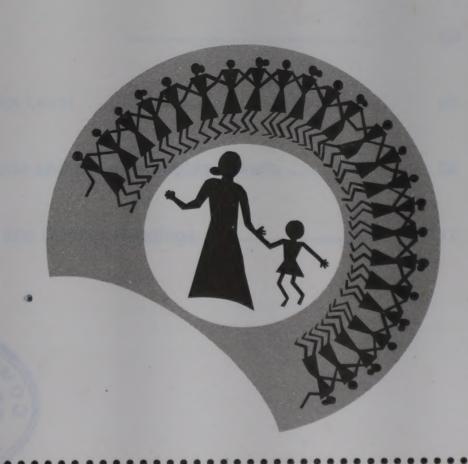
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Book 13

Public Health Resource Network

Legal Obligations of District Health System



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Public Health Resource Society, New Delhi

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National Rural Health Mission

National Health Systems Resource Centre

State Health Resource Centre, Chhattisgarh

ICICI Centre for Child Health and Nutrition

National Institute of Health and Family Welfare

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Public Health Resource Network

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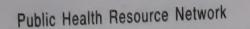
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Preface

Public Health Resource Network (PHRN) aims to provide support to public health practitioners working in the districts in all aspects of district health planning and public health management. The central element of this initiative is a capacity building effort structured as a distance learning programme. This distance learning programme is not a substitute to formal professional public health training and it does not carry with it any guarantees of increased employment or career options. It is meant to support individuals and organizations both within and outside the health department who are committed to working for a more equitable and effective public health system. This programme complements official training and education programmes through an open-ended, more informal and immediate reaching out with information, tools and a diversity of programme options and perspectives. The Health Mission needs a combination of dedication and being of privilege a professional is not one more form professionalism, where - but a competence that anyone willing to put in the time and effort -- and a little expense -- can acquire!! Thus the contact programmes at district, regional and state level would evolve into mechanisms of sharing of resources, and building mutual solidarity amongst those who work for change. The immediate context is the National Rural Health Mission. Hopefully the voluntary network that emerges will contribute over the years to the evolution of a network of district and block level resource groups who provide technical support to all efforts at decentralized planning and decentralized governance and to all societal efforts towards an equitable and just society.

This book, the thirteenth book in the PHRN series, aims to examine the various legal responsibilities that exist at the district level. These are extremely important, but often given very low priority due to lack of information and also lack of public pressure. Issues such as regulation of food safety are immediately



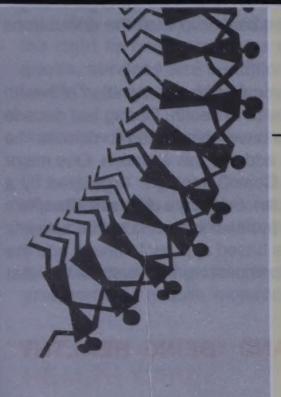
relevant to ill health and disease, specially so in the context of universalized public schemes for food security such as the mid day meal. The implementation of the PC-PNDT Act and the MTP Act, or the lack of it, makes an enormous difference to the success of other strategies for women's health and long term health goals. Thus, the use of legal powers and obligations of the district health system can complement other health strategies significantly, while also demonstrating the health administration's commitment to peoples' rights to health and health care.

We hope the book will provide you with enough insight and information to strengthen the legal instrument of ensuring health and health care to all people from the perspective of health as a fundamental and human right.



Lesson ONE

Understanding Concept and Contours of 'Right to Health'
And its Linkages with Human Rights



In this lesson we shall discuss:

- Relationship of 'right to health' to "attainment of the highest possible level of health"
- Relationship between the 'right to health' and the 'right to health care'
- Features of rights based approach to health
 - The relationship between health rights and human rights
- Relevance of human rights and health rights to health professionals

A large proportion of Indians are unable to attain a reasonable standard of health. Access to even basic health care is difficult for a large part of the population. Increases in socio-economic inequity worsen the situation in health equity, and this in turn could worsen socio economic inequity, resulting in a vicious circle in which the inequities feed and exacerbate each other. There is therefore need for urgent, large-circle in which the inequities feed and exacerbate each other. There is therefore need for urgent, large-scale and effective action to improve this situation. This reality forms the backdrop to all the discussions here about the right to health.

Social activists and health activists have for some time now been advocating the recognition of health rights and the need to build up systems based on a rights based approach to health. During last decade or so, many public health professionals and health care professionals have also begun to discuss the merits of a 'rights based approach to health' as one of the strategies to address this situation. One major initiative to forefront the right to health has been the 'Right to Health Care Campaign' organized by a coalition of over 20 national civil society networks which is called *Jan Swasthya Abhiyan* (People's Health Movement – India). This is an association where public health professionals and social activists participate. In this chapter, we will try to briefly understand what a rights based approach means and the potential of 'right to health' and the 'right to health care' as strategies to improving the health of the vast majority of people.

RELATIONSHIP BETWEEN 'RIGHT TO HEALTH' AND "BEING HEALTHY"

Health is defined as a state of physical, mental and social wellbeing and not merely the absence of disease or infirmity. The attainment of the highest possible level of health has been enshrined as one of the most important social goals. Securing the right to health is not the equivalent of attaining this social goal, but it is an essential part of the process.

When people talk of 'rights', they are talking of things that can be demanded, most of the times from the government or other public bodies or officials or service providers by placing a duty on them. But "being healthy" or "attaining the highest level of health" cannot be demanded from the government or from any public institution Whether any person is healthy or not depends also on a number of factors within the individual, including the individual's genetic and body composition, behaviour, habits and lifestyle, which are largely beyond the purview and control of the government. However, what can be justifiably demanded by people are the basic conditions and services necessary for one to be healthy, just as they demand a right to education or a right to food security. Though the creation of such basic conditions by itself does not ensure good health, in its absence the attainment of a reasonable level of health, let alone the highest possible level, becomes that much more unlikely.

This distinction is brought out aptly in General Comment 14 of the United Nations Committee on Economic, Social and Cultural Rights¹:

¹ This Committee is set up under the International Covenant on Economic, Social and Cultural Rights (ICESCR)



"The right to health is not to be understood as a right to be healthy. ... There are a number of aspects which cannot be addressed solely within the relationship between States and individuals; in particular, good health cannot be ensured by a State, nor can States provide protection against every possible cause of human ill health. Thus, genetic factors, individual susceptibility to ill health and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual's health. Consequently, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health"². (emphasis added)

Similarly a WHO publication on the right to health states that -

"The right to the highest attainable standard of health in international human rights law is a **claim to a set of social arrangements** - norms, institutions, laws, an enabling environment - that can best secure the enjoyment of this right"³. (emphasis added)

It is obvious that this claim to a set of 'facilities, goods, services and conditions', or to a 'set of social arrangements' is quite wide reaching and comprehensive, as will be discussed in the next section.

THE RELATIONSHIP BETWEEN 'RIGHT TO HEALTH' AND 'RIGHT TO HEALTH CARE':

In practice it has often been seen that when people talk about the 'Right to Health' what they actually have in mind is the 'Right to Health Care'. But these are not synonymous.

Health is determined and shaped by several other factors not directly or clearly linked with health as biomedical factors are. While latter do directly deal with a situation of ill-health or disease, they operate in a milieu of several socio-economic and even cultural factors which determine the health status in a more germane way.

The UN Committee on Economic, Social and Cultural Rights has interpreted health in a much larger, non-medicalised, social framework, tightly linking it up with the underlying socio-economic and cultural determinants. The Committee has elaborated upon the "right to the highest attainable standard of health" mandated under Article 12 of International Covenant on Economic, Social and Cultural Rights (ICESCR) to mean:

"as an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health". (emphasis added)

² Committee on Economic, Social And Cultural Rights, Twenty-second session, Geneva, 25 April-12 May 2000, General Comment No. 14, paras 8 & 9 http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument

³ 25 Questions and answers on health and human rights, World Health Organization, 2002

⁴ Para 11, General Comment No. 14 (2000)

The Committee has further stated:

"The right to health is closely related to and dependent upon the realization of other human rights, as contained in the International Bill of Rights, including the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the right to health"5. (emphasis added)

To put it simply, the right to health consists of a combination of two sets of rights:

- 1. The right to underlying health determinants: There are, what are called as "underlying determinants of health", like access to safe drinking water, adequate sanitation, food security, nutrition and housing, healthy occupational and environmental conditions, access to health-related education and information, and a social environment free from violence. All these determinants have a crucial impact on health, and ensuring access to these is essential to secure the right to health.
- 2. The right to health care: Health care includes the entire range of preventive, promotive, curative and rehabilitation services, mainly bio-medical, which are carried out with the primary objective of maintaining or restoring health, including health infrastructure, health human resource/ manpower, drugs and equipment, and all the other facilities for addressing ill health and diseases. These services are largely provided by the health care system, which includes both the public health system and private health care providers.

From the practical point of view, those working in the health sector have two responsibilities both of them being equally important:

A central responsibility for promoting the right to health care, since they usually work in this sector and often have specialized knowledge about health care and the health care system.

A supportive responsibility to promote the right to underlying health determinants (water, food, sanitation, environmental and industrial hygiene, occupational safety, housing, safety from violence and discrimination) although action on these fronts may often be primarily led by other allied movements. In fact, they are well placed to demonstrate the health consequences of violation of the right to health determinants, for instance, showing how denial of food security leads to worsening malnutrition and increased child mortality; how contaminated water leads to outbreaks of diarrhoea and other water borne diseases.

RIGHTS BASED APPROACH TO HEALTH:

Marking a shift from satisfying basic needs ("needs-based" approach) to fulfilling and securing fundamental human rights, United Nations has defined the Rights-Based Approach to any aspect of development as a conceptual framework that integrates "the norms, standards and principles of the international human

⁵ Para 3, General Comment No. 14 (2000)

Understanding Concept and Contours of 'Right to Health' And its Linkages with Human Rights



rights system into the plans, policies and processes of development". United Nations Population Fund (UNFPA) describes a rights-based approach as one that "strives to secure the freedom, well-being and dignity of all people everywhere, within the framework of essential standards and principles, duties and obligations". Therefore, within a rights based approach, every aspect of development, like water, food, housing, health, education, is conceived of as an entitlement to be realized.

Some key features of a rights based approach are:

- Compliance with a set of objective internationally/and nationally accepted standards, principles and norms.
- Democratic/ participatory process with inclusion of range of representatives of different social sections and going beyond government agencies
- Health care seen not as largesse/charity handed down by government to citizens, but as fulfilling its commitment and as performing an essential function for which it was created and which is the reason for its existence.
- As having to address competing needs and interests through a systematic, holistic and integrated approach
- Ensuring health equity
- Framework for implementation which is linked with consequences for non implementation, also called liability, of the "duty bearer" the persons or institutions responsible. A law is thus binding on all who it covers

Some advantages of using the rights approach to health:

There are a number of strengths in the 'rights based approach' to health, which can make it an effective tool for strengthening and reorienting the public health system, to ensure people's access to health related entitlements. Some of these features are⁸:

- A simple slogan like 'Right to Health Care' can be comprehended, at a basic level, by anyone, from an ordinary 'person in the street' to a WHO official. The rights language has a strong universal appeal, and can help a much larger mass of people, beyond health experts and activists, to relate to the basic issue and get involved.
- The health rights approach *empowers individuals, communities and organizations, enabling them* to negotiate for and demand in a specific, concrete way, particular health services *and facilities*.

⁶ United Nations High Commissioner for Human Rights. What is a Rights-Based Approach to Development? Available online: www.unhchr.ch/development/approaches-04.html

⁷ United Nations Population Fund (UNFPA). The Human Rights-Based Approach. Available online: www.unfpa.org/rights/

⁸ Adapted from Abhay Shukla's "A compiled review of the rights approach to health and health care", submitted for publication to 'Beyond the Circle', India, 2007

Once grasped in its essentials, this approach can be wielded by any person or collective, and becomes a source of strength and bargaining power.

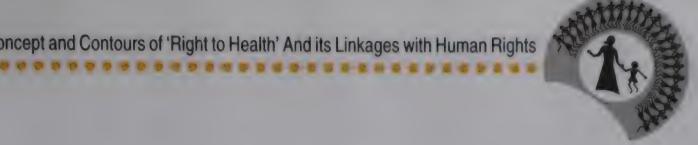
- The health rights approach focuses on functional health outcomes and health service outcomes, and measures all policy changes or declarations in terms of what people actually receive in terms of real entitlements towards their health needs. The rights approach synergises well and provides support to outcome based approaches and provides a corrective to input based assessments ('we have spent so many crores, we have appointed so many staff etc').
- When the idiom of health rights becomes part of the overall discourse, automatically health services become understood as important public resources, to be universally accessible, distinct from commercial goods or services to be purchased in the market. This is important shift of understanding and a recognisation that one cannot leave it to market forces to regulate the supply and consumption of health care services or of access to the determinants of health.
- By their essential character, rights lend themselves to expansion and universalisation. Once certain rights become established, they become a precedent for other groups or marginalized sections to demand similar rights to address their special needs and vulnerabilities. Thus the rights approach naturally strengthens the claims of the most disadvantaged and vulnerable sections of society, and helps us both to challenge discrimination and to ask for attention to the most deprived to ensure that no section of population is directly or indirectly denied their claims to health services.
- Prights once granted cannot be easily reversed. While health policies and programmes may be changed by new governments, sometimes leading to weakening of services, once a 'right' to certain health services or facilities is established, there is certainty to their availability; it is very difficult for any person or authority to take away a right, as that would constitute violation of that right. This becomes a strong basis to maintain and develop the public health system.

THE LINK BETWEEN HEALTH RIGHTS AND HUMAN RIGHTS.

Human rights are the set of core rights every human is entitled to, which define his existence as "human".

Basics of human rights for health service providers to know about:

- Human rights belong to everyone, all of the time, not only certain groups at certain times 'universal'
- Human rights are part of what it means to be a human being hence they are called 'inalienable'. This
 also means that (a) Human rights cannot be 'given' to us, only claimed or fulfilled and (b) Human
 rights cannot be 'taken away' from us, only limited or restricted in some circumstances



- Human rights give expression to a set of core, non-negotiable principles including dignity, equality, respect, fairness and autonomy - that is why they are called "human" rights and they are 'guaranteed'
- Human rights exist as a way of making these core principles real and meaningful in people's lives. public services and in society generally
- Human rights are inter-dependent and indivisible: if you take one away, others are affected too
- In terms of obligations of governments, human rights require authorities to take active steps to protect individuals or groups when they are put at risk by organizations or other individuals
- In terms of obligations of health service providers, human rights are about how health service providers must treat everyone as human beings (Adapted from: Human Rights in Healthcare: A Framework for Local Action, by British Institute of Human Rights & Department of Health, UK)

'basic rights to humane dignified treatment and things I should have access to simply because of the fact I am a human being'

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Linkages between health and human rights:

• Violations or lack of attention to human rights can have serious health consequences; Conversely the impact of ill health and vulnerability to ill health can be reduced by taking steps to respect, protect and fulfill human rights.

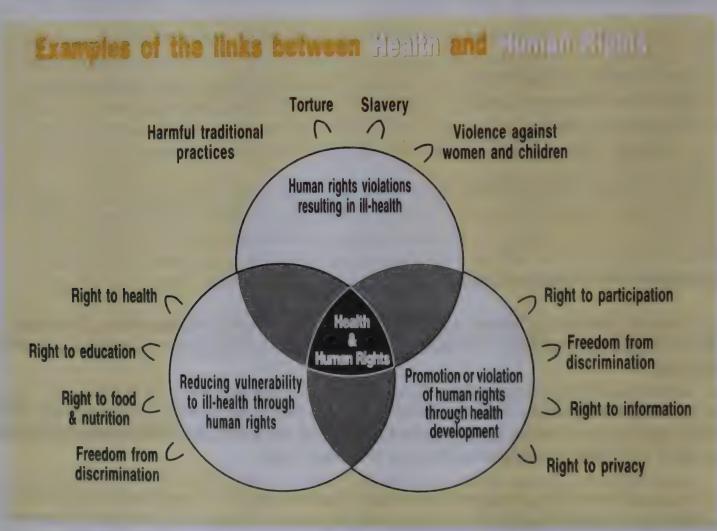
Local action by different sections of society need to identify and draw attention to this linkage. Health care providers need to place before the authorities and before the public the health issues they come a cross which stem from lack of attention to/violation of human rights.

Example: An increasing mortality amongst children due to diarrhea may have hunger and acute malnutrition as an important factor. Health care providers would not only need to bring this to the notice of concerned authorities, but push it through advocacy measures. Trying to build in food provision with health care - to the extent possible could also be tried.

• Health policies and programmes can promote or violate human rights in the ways they are designed or implemented. Public health professionals and administrators designing programmes need to review policy and programmes through this lens. Health care providers should be conscious of ways in which programmes can violate human rights and could choose not to implement them or participate in them. But this could be problematic for an employee.

For example in the years 1976-77 thousands of persons were picked up and forcibly sterilized as a way of achieving our family planning goals. If you were a government doctor working under orders what would you have done? Discuss.

A new policy is introduced to raise user fees for diagnostics at district hospital so as to limit its use and cap the budget. This would work against the poor. If you were an employee of that hospital what could one do? Discuss. If the hospital is obliged to live within the current budget, and needs therefore to limit expenditure how could it handle the situation?



(Picture from 25 Questions and Answers on Health and Human Rights, (Health and human rights publication series, Issue No. 1, 2002, WHO)



RELEVANCE OF HEALTH RIGHTS TO HEALTH PROFESSIONALS:

Many health professionals and authorities feel threatened by the "rights approach" and feel that rights can only be used by health care users and against them. Others look at rights as something that would reduce their professional freedom. Almost always rights are seen as imposing unfair and burdensome obligations and generate fear of punishment or liabilities. But these are not correct views.

It is important for providers to understand that

- a) Rights are not unilateral or only for the users; the providers also have their own rights and can exercise them.
- b) Rights are meant to be creating a framework in which providers and users are collaborators for a fair, equitable and humane system, and not adversaries. The rights approach educates and empower the providers, such that the circumstances for their violations do not occur in the first place. Awareness of people on their rights is increasing. By sensitizing the providers to these issue we prevent violations and perceptions of violation- rather than handle the problem once it has reached a stage of conflict.
- c) Healthcare professionals and planners need this approach to reach the important goal of health equity to ensure nondiscrimination, fairness and equity in access to healthcare and services-of the most vulnerable and marginalized sections of population. It helps them to design schemes that are equitous...
- d) Being most immediately confronted with many of the obstacles to healthcare, health service providers and can direct governmental attention to inadequacies in healthcare services and systéms that violate health rights. Similarly health facility administrators who face the struggles of resource shortages can advocate better for enhanced and rational resource allocation in the language familiar to government officers and legislators.

The health professionals' commitment and role towards social well-being, justice and happiness can therefore be spread and deepened further if they are informed of and sensitive to the 'rights' paradigm.

Conclusion: Health rights as a key strategy must be combined with complementary processes

It is obvious that mere articulation of health rights, while being extremely *necessary*, may not in itself be *sufficient* to bring about the health system changes and larger social changes required to really achieve 'Health for All'. To realistically move towards access to good quality health care and healthy living conditions for all, a combination of the following is also essential:

Large scale social awareness about health and human rights, and about the social determinants of health and about the role individuals and communities would play in attaining the goal of health for all.

Large scale mobilization of social organizations, which can persistently press for fulfillment of these rights, leading to health being put much higher on the social-political agenda;

Legal, constitutional entitlements to essential health services, along with systems to monitor these entitlements and redressal mechanisms to deal with instances of denial of health care;

A well worked out broad programme for universal access to comprehensive health care, backed by substantially increased public health funding, which simultaneously strengthens, integrates and reorients the public health system while regulating the private medical sector and guiding them to contribute to public health goals.

Until the goal of "health for all" is achieved, 'right to health' will be an ethical concept and a value that would inspire health activists and health workers. The rights based approach would be an approach to thinking about the issues of health care, idea and though it may not be fully reached in the immediate future, it would nevertheless continuously show us the way forward.



Review questions:

- 1. What is the meaning of securing right to health? Is it the same as being healthy?
- 2. What is the difference between the right to health and the right to health care?
- 3. What are the strengths of a rights based approach to health?
- 4. What are the basics of human rights that health service providers must know about?
- 5. In what ways does the rights based approach benefit health care professionals.

Application questions:

1. Discuss the common health rights violations that are prevalent in our country and the rights that must be recognized to address them.

- 2. Discuss a model health service facility which would be built and would function with a health rights framework, and how that would make a difference.
- 3. Frame the 'duties' part of the right to healthcare.

Project Assignment:

- 1. Discuss how the inclusion of fundamental right to education in Indian Constitution has affected the status of education services in the country.
- 2. Discuss the experience of another country where the right to health care is a legally recognized right and how it would help to have a constitutionally or statutorily recognized right to healthcare in India.

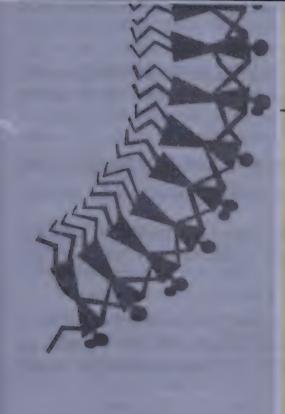
NOTES





Lesson TWO

Legal Recognition of Health Rights: International, Constitutional, and Statutory Health Rights and Obligations



In this lesson we shall discuss:

Meaning of a legal right

Sources of legal recognition of health rights

International law around right to health

Sources and basis of health rights in India – Constitution, domestic legislations and judicial interpretation of fundamental right to life and fundamental right to equality under the Indian Constitution, Directive Principles of State Policy

Normative contents of right to health – the 3 As and a Q (Available, Accessible, Acceptable and of good Quality)

State's health obligations – to respect, protect, and fulfill - health rights, general obligations, core and other obligations.

Enumeration of health rights that are legally recognized most commonly, including Patients' Rights or Users' Rights

Areas of health rights in India, for enactment of health law or other necessary legal intervention

WHAT IS THE MEANING OF A 'LEGAL' RIGHT?

Very simply stated, a right becomes a 'legal' right when it is articulated in any instrument that has the status of law – it could be an international treaty or a national law or a rule or regulation authorized by, and issued under, a law.

Once a right is incorporated in any document that has the validity or status of a law, by its very incorporation such a right becomes elevated to being a legal right. It then gets characterized mainly by all of the following three key features:

- 1. The holder of a legal right is *entitled* to expect his/ her legal rights to be fulfilled in the first place, and when not fulfilled, to demand them.
- 2. The duty holder who is responsible for actualizing a legal right, becomes **bound** to play his prescribed role as per the law towards ensuring that the right holder is provided his/ her legal right and also that he/ she is not deprived of his/ her legal right.
- 3. In case any of the above two does not happen between the right holder and the duty bearer, for a legal right there is a *grievance redressal mechanism* that would ensure that the violation or injustice thus caused is remedied in some recognized manner by an *independent or quasi independent*, *judicial or quasi judicial authority* respectively.

Therefore the clinching feature of a legal right is that it is *justiciable* and *binding* such that the duty holder who fails to perform his/ her obligations suffers legal consequences for such non-performance, either under civil law (entailing corrective or restoratory orders, like, for performance, injunction or compensation) or under criminal law (entailing some punishment like imprisonment or fine).

WHAT ARE THE SOURCES OF LEGAL RECOGNITION OF HEALTH RIGHTS?

Health rights are legally recognized through the following legal systems and the legal instruments created within those systems:

- 1. International legal system
- 2. National or domestic law Constitution, Central and State legislations, Rules/ Regulations/ Orders issued under the statutes



Section 1:

International legal systems:

International legal system comprises all the laws that recognize the rights of individuals throughout the world principally vis-à-vis the commensurate obligations of the governments, and sets uniform and widely accepted international or regional standards that the countries across the globe, or region respectively, are expected to respect and comply with. Such laws could be through treaties, or based on customary rules and practices, like the right to a fair trial or it could be based on international judicial decisions of the International criminal court. Pronouncements, resolutions and declarations of the General Assembly, have the consensus of all countries and have a persuasive value and are seen as general principles.

Some of the constituents of International Legal System are:

- ▶ ► The Universal Declaration of Human Rights (UDHR), 1948
- ▶ ► The major human rights treaties that have been signed under the aegis of United Nations (UN):
 - International Covenant on Civil and Political Rights (ICCPR), 1966
 - International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966
 - Convention on Elimination of All Forms of Racial Discrimination (CERD), 1965
 - Convention against Torture (CAT), 1975
 - Convention on Elimination of All Forms of Discrimination Against Women (CEDAW), 1979
 - Convention on the Rights of the Child (CRC) 1989
 - Convention on Rights of Persons with Disabilities (CRPD), 2007

>> International Declarations:

For instance, some of the declarations relevant to health rights are: Declaration of Alma Ata (1978), Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (1991), Declaration on the Elimination of Violence against Wornen (1993), Declaration on the Right to Development (Vienna Declaration and Programme of Action) (1993), Declaration on the rights of mentally retarded persons, 1971, Declaration on the Rights of Disabled Persons (1975), Programme of Action the International Conference on Population and Development (ICPD, 1994, Cairo), Beijing Declaration (1995), International guidelines on HIV and human rights, 1997), Declaration of Commitment on HIV/AIDS, '. International Health Regulations, 2005

It is pertinent to mention that the UDHR as well as almost all the Treaties/ Conventions/ Covenants mentioned above contain several obligations of the signatory governments towards health, either generally (like the ICESCR) or for particular sections of population (like CEDAW for women and CRC for children), which are given in the box/appendix:

✓ Universal Declaration of Human Rights, Article 25:

"1. Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

2. Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection".

✓ International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 12:

- "1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".
- 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
- (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
- (b) The improvement of all aspects of environmental and industrial hygiene;
- (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

Also relevant are Article 7 (family related health rights of women and children) and Article 10 (safe and healthy working conditions) of the ICESCR.

✓ Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), Article 12:

- "1. States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.
- 2. Notwithstanding the provisions of paragraph I of this article, States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation".

Also relevan't are Article 10 (educational information to help to ensure the health and well-being of women and families), Article 11 (occupational safety of women and maternity benefits) and Article



14 (health of rural women) of CEDAW.

Convention on the Rights of the Child (CRC), Article 24:

- "1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.
- 2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:
- (a) To diminish infant and child mortality;
- (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;
- (c) To combat disease and malnutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;
- (d) To ensure appropriate pre-natal and post-natal health care for mothers;
- (e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents:
- (f) To develop preventive health care, guidance for parents and family planning education and services.
- 3. States Parties shall take all effective and appropriate measures with a view to abolishing traditional practices prejudicial to the health of children.
- 4. States Parties undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries".

Also relevant are **Article 17** (access to information aimed at the promotion of the child's well-being and physical and mental health), **Article 23** (health of children with disabilities), **Article 25** (periodic review of care, protection or treatment of physical or mental health of a child), **Article 32** (protection from occupational hazards and economic exploitation), and **Article 39** (physical and psychological

recovery and social reintegration of a child victim).

Convention on the Elimination of All Forms of Racial Discrimination (CERD) Article 5: "In compliance with the fundamental obligations laid down in Article 2 of this Convention, States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, notably in the enjoyment of the following rights: ...

(iv) The right to public health, medical care, social security and social services;..."

Convention on Rights of Persons with Disabilities, Article 25:

"States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation. In particular, States Parties shall:

- a) Provide persons with disabilities with the same range, quality and standard of free or affordable health care and programmes as provided to other persons, including in the area of sexual and reproductive health and population-based public health programmes;
- b) Provide those health services needed by persons with disabilities specifically because of their disabilities, including early identification and intervention as appropriate, and services designed to minimize and prevent further disabilities, including among children and older persons;
- c) Provide these health services as close as possible to people's own communities, including in rural areas:
- d) Require health professionals to provide care of the same quality to persons with disabilities as to others, including on the basis of free and informed consent by, inter alia, raising awareness of the human rights, dignity, autonomy and needs of persons with disabilities through training and the promulgation of ethical standards for public and private health care;
- e) Prohibit discrimination against persons with disabilities in the provision of health insurance, and life insurance where such insurance is permitted by national law, which shall be provided in a fair and reasonable manner:
- f) Prevent discriminatory denial of health care or health services or food and fluids on the basis of disability".



Section 2:

National/ domestic legal system for recognition of health rights in India:

In any national/domestic legal system, there can be basically three sources of legal recognition of health rights:

- 1. Indian Constitution; and
- 2. Indian Statutes (or Acts, as domestic legislations are commonly called);
- 3. Judge made law (since under the Indian Constitution, the judgments of Supreme Court and High Court have the same status as the law of the land)

However, when we look at right to health and healthcare in the legal and constitutional framework of India, it is clearly evident that neither the Constitution or the Statutes of India as yet accord health and healthcare the status of rights as such. Indian Constitution lacks a provision similar to Section 27 of the South African Constitution that encompasses a fundamental right to health care services including reproductive health care. Further, the Indian legal system lacks any dedicated law comprehensively encompassing health or even health care rights per se, like the South African National Health Act, 2004.

India does have laws that cover selective aspects of health and heaithcare.

Indian laws covering selective aspects of health and health care:

Epidemic Diseases Act, 1897; Drugs and Cosmetics Act, 1940; Drugs (Control) Act, 1950; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954; Prevention of Food Adulteration Act, 1954; Maternity Benefit Act, 1961, Registration of Births and Deaths Act, 1969; Medical Termination of Pregnancy Act, 1971; Water (Prevention and Control of Pollution) Act, 1974; Narcotic Drugs and Psychotropic Substances Act, 1985; Air (Prevention and Control of Pollution) Amendment Act, 1987; Mental Health Act, 1987; Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988; Transplantation of Human Organs Act 1994; Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; National Environment Tribunal Act, 1995; Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995; National Trust for Welfare of Persons with Autism, Cerebral Palsy, Mental Retardation and Multiple Disabilities Act, 1999; Hospital and Clinical Establishment Registration Acts of different states; laws to deal with negligence like Consumer Protection Act.

However, there is no clear articulation of the health right in most of these legislations. Nevertheless, despite this near absence of articulation of 'health rights' per se in the Indian Constitution, Nevertheless, despite this near absence of articulation of 'health rights' per se in the Indian Constitution, and there are ample spaces within the Indian Constitution that can be and have been utilized to imply, and obtain health rights. Mainly, two parts of the Indian Constitution have these spaces – directly, the chapter on the Directive Principles of State Policy and indirectly but very strongly, the chapter on Fundamental Rights.

Right to health under fundamental right to life: Article 21 of the Indian Constitution states: "21. Protection of life and personal liberty: No person shall be deprived of his life or personal liberty except according to procedure established by law".

This is popularly known as the fundamental right to life. Read literally this right reads appears to be a negative right with a narrow focus, i.e., a right against any threat to liberty or danger to life, the Indian Supreme Court has developed this into an entire area of positive rights. Through several judgments Supreme Court has expanded the fundamental right to life guaranteed under Article 21 of the Constitution into an overarching right under which several other positive rights are subsumed as necessary components of life. Given in box 4 is a number of landmark judgements which provide the legal basis for right to health.

In the eighties, Supreme Court held in Francis Coralie v. Union Territory of Delhi (1981) I SCC 608: (AIR 1981 SC 746) that the right to life includes the right to live with human dignity and all that goes along with it namely, the bare necessities of life such as adequate nutrition, clothing and shelter over the head and facilities for reading, writing and expressing oneself in diverse forms, free movement and co-mingling with fellow human begins. It was in the same vein that Supreme Court interpreted right to life in the Chameli Singh v. State of U.P. (1996) 2 SCC 549: "Right to life guaranteed in any civilized society implies the right to food, water, decent environment, education, medical care and shelter... All civil, political, social and cultural rights enshrined in the Universal Declaration of Human Rights or under the Constitution of India cannot be exercised without these basic human rights".

In Paschim Banga Khet Mazdoor Samity and others v. State of West Bengal and another, 1996), the Supreme Court of India ruled that: "Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare state. ... Article 21 imposes an obligation on the State to safeguard the right to life of every person. ... The Government hospitals run by the State and the medical officers employed therein are duty bound to extend medical assistance for preserving human life. Failure on the part of a Government hospital to provide timely medical treatment to a person in need of such treatment results in a violation of his right to life guaranteed under Article 21". Similarly in the case Bandhua Mukti Morcha v. Union of India and others, 1982 concerning bonded workers, the Supreme Court gave



orders interpreting Article 21 as mandating the right to medical facilities for the workers. (emphasis added)

In several other cases the Supreme Court and High Courts have read the right to health and health care under right to life under Article 21 of Constitution, some of which are as follows: That right to health is a fundamental right was held in CESC Ltd. vs. Subash Chandra Bose, (AIR 1992 SC 573, 585); everyone is entitled to adequate health care was held in Mahendra Pratap Singh vs. Orissa State AIR 1997 Ori 37; health and health care of workers is an essential component of right to life was held in CERC vs. Union of India, (1995) 3 SCC 42 and Kirloskar Brothers Ltd. vs. Employees' State Insurance Corporation, (1996) 2 SCC 682, and in State of Punjab and others v. Mohinder Singh Chawla and others 1997 (2) SCC 83; right to health care of government employees is integral to right to life was held in State of Punjab vs. Mohinder Singh Chawla 1997 2 SCC 83; emergency health care as fundamental right to life was held in Paschim Banga Khet Mazdoor Samiti vs. State of W.B. (1996) 4 SCC 37.

Some of the important fundamental rights which have thus been recognized as part of right to life under Article 21 of constitution, and which are pertinent to right to health are: right to food (People's Union for Civil Liberties v. Union of India & others Writ Petition No. 196 of 2001); right to pollution-free water and air (Subhash Kumar vs. State of Bihar, AIR 1991 SC 420); right against environmental, ecological, air and water pollution (Virender Gaur vs. State of Haryana, 1995 (2) SCC 577); right to clean water (Attakoya Thangal Vs. Union of India [1990(1) KLT 580]); right to sanitation (Municipal Council, Ratlam vs. Vardhichand & others, 1980 CriLJ 1075); right to housing (For instance in Shantistar Builders v. Narayan Khimalal Tortame: (1990) 1 SCC 520), P.G. Gupta v. State of Gujarat (1995) Supp 2 SCC 182), Chameli Singh v. State of U.P.: (1996) 2 SCC 549, Nawab Khan's case (Ahmedabad Municipal Corporation v. Nawab Khan Gulab Khan & others (1997) 11 SCC 121)), right to education (Bandhua Mukti Morcha v. Union of India (1984 3 SCC 161), Mohini Jain v. State of Karnataka (1992) 3 SCC 666) and Unnikrishnan J.P. & others v. State of Andhra Pradesh & others Union of India (1993) 1 SCC 645), and so on.

Right to equality, affirmative action, positive discrimination:

Also relevant for our present purpose is the fundamental right to equality under Article 14 of the Constitution of India which states that: "The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India". This is important to highlight the special place of health equity in law, and the duty of the state to ensure that deprived and marginalized sections also have an equitable access to quality health care.

Judicial pronouncements from the Supreme Court as well as the High Courts of the country have left no doubt that it is not merely "formal" equality that the Constitution guarantees. Mere formal equality would

mean that the society would simply reflect its extant hierarchy and order in the distribution of resources and would oblige the state to only be responsible for treating all persons in the same manner, based on objective standards. However, it is the model of "substantive" equality that the Indian Constitution has espoused under Article 14, as opposed to "formal" equality. This implies that only the equals must be treated as equals and that unequals may not be treated as equals. This makes it the government's responsibility to ensure that the systemic, socio-economic vulnerabilities, e.g., of women, children, rural populations; and historical conditions of disadvantaged classes of persons, e.g., scheduled classes and tribes, are taken into account in providing equal status and equal opportunities. Simply put, this notion of equality means that the laws may not have universal application for all persons who are not by nature, attainment, historical reasons or any other circumstance in the same position and hence the varying needs of different classes of persons may require separate treatment, the only condition being that the classification for separate treatment should be rational and must further the objective of that law and be linked with it.

In effect, this substantive equality has two implications: Firstly, in any event this paradigm rules out any denial or discrimination against any individual or class, on any arbitrary or unreasonable basis. Secondly, and more importantly, the substantive equality paradigm permits "affirmative action" by way of special laws creating special rights and "positive discrimination" by way of reservations in favour of weaker classes of society to bring them on par with the general population. For instance, the special provisions for ensuring the health and access to health care of rural people (under the NRHM) or women and children (under the RCH policy) are justified under the right to equality and lie within this mandate of Article 14 of the Constitution of India. Therefore under Article 14 the principle of non-discrimination in relation to health facilities, goods and services is legally enforceable.

In some many judgments the Supreme Court has responded to writ petitions filed under Article 32 of the Constitution of India, for violation of both Article 14 and 21 of the Constitution. For instance, in several writ petitions filed against the inhuman treatment meted out to persons with mental disabilities in institutions for their care and treatment, Supreme Court laid down guidelines on their living and treatment conditions, education, training and rehabilitation facilities in such institutions (Rakesh Chandra Narayan v. State of Bihar (1986 (Supp) SCC 576: AIR 1989 SC 348) and B.R. Kapoor v. Union of India (AIR 1990 SC 662)) or for the care of mentally sick undertrials languishing in jails (Veena Sethi v. State of Bihar & others (1982) 2 SCC 583 and Sheela Barse v. Union of India: (1993) 4 SCC 204).

Apart from Articles 14 and 21, some of the other fundamental rights that have a bearing on public health are: Article 15 (right to non-discrimination), Article 17 (abolition of untouchability); Article 23 (prohibition of traffic in human beings and forced labour); and Article 24 (prohibition of employment of children in factories, etc.).

It is pertinent to mention that any violation of a fundamental right, which can be attributed to the government's action or inaction, can be taken to the constitutional courts (Supreme Court and High Courts) through



Writ Petitions under Article 32 and 226 of the Constitution respectively. However, the fundamental rights cannot be ordinarily invoked against a private person or body.

Fundamental rights under the Indian Constitution which are relevant to public health

- 14. The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.
- 21. Protection of life and personal liberty: No person shall be deprived of his life or personal liberty except according to procedure established by law.
- 15. Prohibition of discrimination on grounds of religion, race, caste, sex or place of birth.—
- (1) The State shall not discriminate against any citizen on grounds only of religion, race, caste, sex, place of birth or any of them.
- (2) No citizen shall, on grounds only of religion, race, caste, sex, place of birth or any of them, be subject to any disability, liability, restriction or condition with regard to—
- (a) access to shops, public restaurants, hotels and places of public entertainment; or
- (b) the use of wells, tanks, bathing ghats, roads and places of public resort maintained wholly or partly out of State funds or dedicated to the use of the general public.
- (3) Nothing in this article shall prevent the State from making any special provision for women and children.
- (4) Nothing in this article or in clause (2) of article 29 shall prevent the State from making any special provision for the advancement of any socially and educationally backward classes of citizens or for the Scheduled Castes and the Scheduled Tribes.
- 23. Prohibition of traffic in human beings and forced labour.—(1) Traffic in human beings and begar and other similar forms of forced labour are prohibited and any contravention of this provision shall be an offence punishable in accordance with law.
- (2) Nothing in this article shall prevent the State from imposing compulsory service for public purposes, and in imposing such service the State shall not make any discrimination on grounds only of religion, race, caste or class or any of them.

- 24. Prohibition of employment of children in factories, etc. —No child below the age of fourteen years shall be employed to work in any factory or mine or engaged in any other hazardous employment.
- 17. Abolition of Untouchability.—"Untouchability" is abolished and its practice in any form is forbidden. The enforcement of any disability arising out of "Untouchability" shall be an offence punishable in accordance with law.

Directive Principles of State Policy:

Even though they are not *justiciable* which means that they cannot be invoked to demand anything as a mater of right, or to get them enforced in any court of law, there are some Directive Principles of State Policy in the Constitution which also lend support to the health rights. Directive Principles have often been used by the Indian constitutional courts to adjust and expand the ambit of the fundamental rights, and also to interpret other constitutional provisions. Recently the courts have even been issuing directions to the government and various administrative authorities to take positive action to remove grievances caused by non-implementation of the directive principles.

Indian Constitution also urges the governments, under the 'Directive Principles of State Policy', to strive to provide to everyone certain vital public health conditions such as eliminating inequalities in status, facilities and opportunities (Article 38); health of workers, men, women and children (Article 39); right to work, education and public assistance in certain cases (Article 41); just and humane conditions of work and maternity relief (Article 42); raised level of nutrition and the standard of living and improvement of public health (Article 47); and protect and improve environment (Article 48A); and identifies certain concomitant 'Fundamental Duties' like obligating every citizen to denounce practices derogatory to the dignity of women; and to protect and improve the natural environment (Article 51);

In Municipal Council, Ratlam vs. Vardhichand & Others, 1980 CriLJ 1075, while rejecting the plea of monetary constraints for performing its duty of cleaning up the garbage, advanced by the municipal corporation, the Supreme Court observed: "The State will realize that Article 47 makes it a paramount principle of governance that steps are taken for the improvement of public health as amongst its primary duties".



Directive Principles of State Policy of Indian Constitution Relevant to Public Health

- 37. Application of the principles contained in this Part: The provisions contained in this Part shall not be enforceable by any court, but the principles therein laid down are nevertheless fundamental in the governance of the country and it shall be the duty of the State to apply these principles in making laws.
- 38. State to secure a social order for the promotion of welfare of the people: (1) The State shall strive to promote the welfare of the people by securing and protecting as effectively as it may a social order in which justice, social, economic and political, shall inform all the institutions of the national life.
- (2) The State shall, in particular, strive to minimise the inequalities in income, and endeavour to eliminate inequalities in status, facilities and opportunities, not only amongst individuals but also amongst groups of people residing in different areas or engaged in different vocations.
- 39. Certain principles of policy to be followed by the State: The State shall, in particular, direct its policy towards securing—
- (a) that the citizens, men and women equally, have the right to an adequate means of livelihood;
- (b) that the ownership and control of the material resources of the community are so distributed as best to subserve the common good;
- (c) that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment;
- (d) that there is equal pay for equal work for both men and women;
- (e) that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength;
- (f) that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment.
- 47. Duty of the State to raise the level of nutrition and the standard of living and to improve public health: The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health.

- 42. Provision for just and humane conditions of work and maternity relief: The State shall make provision for securing just and humane conditions of work and for maternity relief.
- 41. Right to work, to education and to public assistance in certain cases: The State shall, within the limits of its economic capacity and development, make effective provision for securing the right to work, to education and to public assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want.
- 48A. Protection and improvement of environment and safeguarding of forests and wild life: The State shall endeavour to protect and improve the environment and to safeguard the forests and wild life of the country.

(emphasis supplied)

While there used to be a clear difference between Fundamental Right and Directive Principles (especially in as much as the latter are technically not enforceable), the two have increasingly been merged, as a result of creative interpretations under Indian Supreme Court rulings. We will look at the judgments of Indian Supreme Court and High Courts in greater detail in a later chapter in this book, that will demonstrate this better.

NORMATIVE CONTENTS OF RIGHT TO HEALTH - 3 AS AND A Q:

The normative contents of right to health have been considerably elaborated upon in the aforementioned General Comment 14 of CESCR (to elaborate on Article 12 of the ICSCR) which has constructed the right into basically four pillars:

- 1. Availability
- 2. Accessibility
- 3. Acceptability
- 4. Quality
- (a) Availability. Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party. The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State's developmental level. They will include, however, the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs (as defined by the WHO Action Programme on Essential Drugs).



- (b) Accessibility. Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State. Accessibility has four overlapping dimensions:
 - (i) **Non-discrimination:** Health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any grounds.
 - (ii) **Physical accessibility:** Health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS. Accessibility also implies that underlying determinants of health, such as safe and potable water and adequate sanitation facilities, are within safe physical reach, including in rural areas. Accessibility further includes adequate access to buildings for persons with disabilities.
 - (iii) **Economic accessibility (affordability):** Health facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.
 - (iv) Information accessibility: Accessibility includes the right to seek, receive and impart information and ideas concerning health issues. However, accessibility of information should not impair the right to have personal health data treated with confidentiality.
- (c) **Acceptability:** All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned.
- (d) **Quality:** As well as being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, *inter alia*, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.

STATE'S OBLIGATIONS TOWARDS HEALTH RIGHTS:

A. To respect, protect, and fulfill health rights:

The obligations of the governments have been elaborately explained in the aforementioned CESCR's General Comment No. 14 to Article 12 of ICESCR, which explains them as the following inter-related and

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partially overlapping obligations:

(a) The obligation to respect which requires the governments to refrain from denying or interfering, directly or indirectly, with the enjoyment of the right to health by any individual or group mentioned hereunder;

(b) The obligation to protect which requires the governments to take measures that prevent third parties

from interfering with the health rights mentioned herein; and

(c) The obligation to fulfill which requires the governments to facilitate, provide and promote the health rights mentioned herein, by adopting appropriate legislative, administrative, budgetary, judicial, promotional and other measures.

To bring clarity to, suggest and emphasise some instances of obligations that flow from the combined effect of the three abovementioned obligations, the CESCR has enumerated illustrations of each kind of obligations, as follows:

Illustrations of the State's obligations to respect, protect, fulfill health rights

Illustrations of obligation to respect:

a) Refraining from denying or limiting equal access for all persons or groups, including prisoners or detainees, minorities, asylum seekers and illegal immigrants, to preventive, curative and/ or palliative health services;

b) Refraining from applying coercive medical treatments (unless on an exceptional basis, but even

then with safeguards of applicable international standards);

c) Refraining from limiting access to contraceptives and other means of maintaining sexual and reproductive health;

d) Refraining from censoring, withholding or intentionally misrepresenting health-related information,

including sexual education and information;

e) Refraining from preventing people's participation in health-related matters;

- f) Refraining from limiting access to health services as a punitive measure, e.g. during armed conflicts, in violation of international humanitarian law;
- g) Refraining from prohibiting or impeding traditional preventive care, healing practices and medicines;

h) Refraining from marketing unsafe drugs;

- Abstaining from enforcing discriminatory practices as a government policy; and i)
- Abstaining from imposing discriminatory practices relating to women's health status and needs.

Illustrations of obligation to protect:

(i) Adopting legislation or taking other measures ensuring equal access to health care and healthrelated services provided by third parties, including individuals, communities, private sector bodies, and non governmental organizations (national and international);

(ii) Regulating public as well as private health sector to ensure availability, accessibility, acceptability and quality of health facilities, goods and services;

Regulating medical practitioners and other health professionals and service providers so that (iii) they meet appropriate standards of education, infrastructure, skills and practices;



- (iv) Regulating clinical trials, medical research and scientific experiments on human beings;
- (v) Regulating use of technologies that may affect health;
- (vi) Ensuring that harmful social or traditional practices do not interfere with access to appropriate medical treatment;
- (vii) Preventing third parties, including individuals, families, communities, organizations, from coercing women to undergo traditional practices, like child marriages, devadasi custom, other ways of socially sanctioned forced prostitution;
- (viii) Preventing violence against vulnerable or marginalized groups of society, in particular women, children, adolescents and older persons; and
- (ix) Preventing third parties from limiting people's equal access to health-related information and services.

Illustrations of obligation to fulfill:

- (i) Giving recognition to the right to health comprehensively, preferably by way of laws on all health related areas; undertaking legislation of new laws and/ or amendment of existing laws;
- (ii) Adopting health policies and appropriate strategies with plans of action for realizing the right to health:
- (iii) Ensuring provision of a sufficient number of functional hospitals, clinics and other health-related facilities;
- (iv) Laying down standards (like IPHS) and norms towards quality assurance and improvement; protocols for treatment and other medical interventions;
- (v) Ensuring appropriate training of doctors and other medical personnel;
- (vi) Ensuring equal health care access to all, including preventive programmes against major infectious diseases; equal access for all to the underlying determinants of health;
- (vii) Taking positive measures that enable and assist individuals and communities to enjoy the right to health, when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal;
- (viii) Ensuring that public health infrastructures provide for sexual and reproductive health services, including safe motherhood, particularly in rural areas;
- (ix) Promoting and supporting establishment of institutions providing counseling and mental health services, with due regard to equitable distribution throughout the country;
- Promoting medical research and health education, as well as information campaigns, particularly with respect to HIV/AIDS, sexual and reproductive health, traditional practices, domestic violence, healthy lifestyles, consumption of alcohol, cigarettes, drugs and other harmful substances;
- (xi) Adopting measures against environmental and occupational health hazards and against any other threat as demonstrated by epidemiological data;
- (xii) Formulating and implementing policies aimed at reducing and eliminating pollution of air, water and soil;
- (xiii) Formulating, implementing and periodically reviewing policies to minimize the risk of

occupational accidents and diseases, and ensuring occupational safety;

Fostering recognition of factors favouring positive health results, e.g. health research and (xiv) provision of health information;

Ensuring that health services are culturally appropriate and that health care staff are trained to recognize and respond to the specific needs of vulnerable or marginalized groups; (xv)

Supporting people in making informed choices about their health. (xvi)

B. General legal obligations

While the ICESCR provides for progressive realization and acknowledges the constraints due to the limits of available resources, it also imposes on States Parties various obligations which are of immediate effect. For instance, the States Parties have immediate obligations in relation to the right to health, such as the guarantee that the right will be exercised without discrimination of any kind (Article 2.2 of ICESCR) and the obligation to take steps towards the full realization of Article 12 (Article 2.1), led for instance by the obligation to allocate adequate budgets for health, and to undertake appropriate health planning and monitoring. Such steps must be immediate, deliberate, concrete and targeted towards the full realization of the right to health.

Keeping in view the mammoth task involved in ensuring health rights to everyone, the ICESCR also provides ample space for "progressive realization" of the right to health over a period of time without taking away the urgency or the obligations and without absolving the governments from their obligations to keep themselves on their toes, without any complacence, which would in effect rob their obligations of all meaningful content. Rather, progressive realization means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 12.

Also, there is a strong presumption that retrogressive measures taken in relation to the right to health are not permissible. If any deliberately retrogressive measures are taken, the State party has the burden of proving that they have been introduced after the most careful consideration of all alternatives, i.e., they are the least restrictive alternatives; and that they are duly justified by reference to the totality of the rights framework, in the context of the full use of the State party's maximum available resources.

C. Specific legal obligations:

Perhaps in keeping with the scheme of progressive realization of health rights carried in the ICESCR, the CESCR has created a division of core obligations and other obligations of comparable priority, the former being obligations that must be fulfilled by the governments forthwith, without any delay or excuse such that their non-fulfillment would not be tolerated in any case.



(a) Core obligations:

The governments have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the health rights enunciated in the aforementioned international law/ Covenants, including essential primary health care. Read in conjunction with more contemporary instruments, such as the Alma-Ata Declaration, the Cairo Programme of Action of the International Conference on Population and Development, the ICESCR provides compelling guidance on the core obligations arising from its Article 12. Accordingly, these core obligations include at least the following obligations:

- (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups;
- (b) To ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone;
- (c) To ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;
- (d) To provide essential drugs, as from time to time defined by the WHO;
- (e) To ensure equitable distribution of all health facilities, goods and services;
- (f) To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.

Obligations of comparable priority:

- (a) To ensure reproductive, maternal (pre-natal as well as post-natal) and child health care;
- (b) To provide effective preventive measures against the major infectious diseases occurring in the communities;
- (c) To take measures to prevent, treat and control epidemic and endemic diseases;
- (d) To provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them;
- (e) To provide appropriate training for health personnel, including education on health and human rights.

HEALTH RIGHTS THAT ARE COMMONLY LEGALLY RECOGNIZED:

Following are some of the health rights that have been accorded legal recognition:

1. Rights related to human rights and values in health care:

The international instruments on human rights cited earlier should be understood as applying also specifically in the health care setting, and it should therefore be noted that the human values expressed in those instruments shall be reflected in the health care system. It should also be noted that where exceptional limitations are imposed on the rights of patients, these must be in accordance with human rights instruments and have a legal base in the law of the country. It may be further observed that the rights specified below carry a matching responsibility to act with due concern for the health of others and for their same rights.

1.1 Everyone has the right to respect of his or her person as a human being.

1.2 Everyone has the right to self-determination (also called as right to autonomy or choice).

1.3 Everyone has the right to physical and mental integrity and to the security of his or her person.

1.4 Everyone has the right to respect for his or her privacy and the right to dignity.

1.5 Everyone has a right to be treated without any arbitrary discrimination.

1.6 Everyone has the right to have his or her moral and cultural values and religious and philosophical

convictions respected.

1.7 Everyone has the right to such protection of health as is afforded by appropriate measures for disease prevention and health care, and to the opportunity to pursue his or her own highest attainable level of health.

2. Rights related to information:

- 2.1 Information about health services and how best to use them is to be made available to the public in order to benefit all those concerned.
- 2.2 Users have the right to be fully informed about their health status, including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment; and about the diagnosis, prognosis and progress of treatment.
- 2.3 Information may only be withheld from users exceptionally when there is good reason to believe that this information would without any expectation of obvious positive effects cause them serious harm.
- 2.4 Information must be communicated to the user in a way appropriate to the latter's capacity for understanding, minimizing the use of unfamiliar technical terminology. If the user does not speak the common language, some form of interpreting should be available.
- 2.5 Users have the right to be informed, at their explicit request.
- 2.6 Users have the right to choose who, if any one, should be informed on their behalf

2.7 Users should have the possibility of obtaining a second opinion.

2.8 When admitted to a health care establishment, users should be informed of the identity and professional



- status of the health care providers taking care of them and of any rules and routines which would bear on their stay and care.
- 2.9 Users have a right that complete medical records be maintained for each of them, and to request and be given a written summary of their diagnosis, treatment and care on discharge from a health care establishment.

3. Rights related to consent:

- 3.1 The informed consent of the user is a prerequisite for any medical intervention.
- 3.2 A user has the right to refuse or to halt a medical intervention. The implications of refusing or halting such an intervention must be carefully explained to the user.
- 3.3 When a user is unable to express his or her will and a medical intervention is urgently needed, the consent of the user may be presumed, unless it is obvious from a previous declared expression of will that consent would be refused in the situation.
- 3.4 When the consent of a legal representative is required and the proposed intervention is urgently needed, that intervention may be made if it is not possible to obtain, in time, the representative's consent.
- 3.5 When the consent of a legal representative is required, users (whether minor or adult) must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.
- 3.6 If a legal representative refuses to give consent and the physician or other provider is of the opinion that the intervention is in the interest of the user, then the decision must be referred to a court or some form of arbitration.
- 3.7 In all other situations where the user is unable to give informed consent and where there is no legal representative or representative designated by the user for this purpose, appropriate measures should be taken to provide for a substitute decision making process, taking into account what is known and, to the greatest extent possible, what may be presumed about the wishes of the user.
- 3.8 The consent of the user is required for the preservation and use of all substances of the human body. Consent may be presumed when the substances are to be used in the current course of diagnosis, treatment and care of that user.
- 3.9 The informed consent of the user is needed for participation in clinical teaching.
- 3.10 The informed consent of the user is a prerequisite for participation in scientific research. All protocols must be submitted to proper ethical review procedures. Such research should not be carried out on those who are unable to express their will, unless the consent of a legal representative has been obtained and the research would likely be in the interest of the user.

As an exception to the requirement of involvement being in the interest of the user, an incapacitated person may be involved in observational research which is not of direct benefit to his or her health provided that that person offers no objection, that the risk and burden is minimal, that the research is of significant value and that no alternative methods and other research subjects are available.

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4. Rights related to confidentiality and privacy:

4.1 All information about a user's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind must be kept confidential, even after death.

Confidential information can only be disclosed if the user gives explicit consent or if the law expressly provides for this. Consent may be presumed where disclosure is to other health care providers involved in that user's treatment.

4.3 All identifiable user data must be protected. The protection of the data must be appropriate to the manner of their storage. Human substances from which identifiable data can be derived must be

likewise protected.

4.4 Users have the right of access to their medical files and technical records and to any other files and records pertaining to their diagnosis, treatment and care and to receive a copy of their own files and records or parts thereof. Such access excludes data concerning third parties.

4.5 Users have the right to require the correction, completion, deletion, clarification and/or updating of personal and medical data concerning them which are inaccurate, incomplete, ambiguous or outdated,

or which are not relevant to the purposes of diagnosis, treatment and care.

4.6 There can be no intrusion into a user's private and family life unless and only if, in addition to the user consenting to it, it can be justified as necessary to the user's diagnosis, treatment and care.

- 4.7 Medical interventions may only be carried out when there is proper respect shown for the privacy of the individual. This means that a given intervention may be carried out only in the presence of those persons who are necessary for the intervention unless the user consents or requests otherwise.
- 4.8 Users admitted to health care establishments have the right to expect physical facilities which ensure privacy, particularly when health care providers are offering them personal care or carrying out examinations and treatment.

5. Rights related to health care and treatment:

- 5.1 Everyone has the right to receive such health care as is appropriate to his or her health needs, including preventive care and activities aimed at health promotion. Services should be continuously available and accessible to all equitably, without discrimination and according to the financial, human and material resources which can be made available in a given society.
- 5.2 Users have a collective right to some form of representation at each level of the health care system in matters pertaining to the planning and evaluation of services, including the range, quality and functioning of the care provided.
- 5.3 Users have the right to a quality of care which is marked both by high technical standards and by a humane relationship between the user and health care providers.
- 5.4 Users have the right to continuity of care, including cooperation between all health care providers and/or establishments which may be involved in their diagnosis, treatment and care.
- 5.5 In circumstances where a choice must be made by providers between potential users for a particular treatment which is in limited supply, all such users are entitled to a fair selection procedure for that treatment. That choice must be based on medical criteria and made without discrimination.
- 5.6 Users have the right to choose and change their own physician or other health care provider and



health care establishment, provided that it is compatible with the functioning of the health care system.

- 5.7 Users for whom there are no longer medical grounds for continued stay in a health care establishment are entitled to a full explanation before they can be transferred to another establishment or sent home. Transfer can only take place after another health care establishment has agreed to accept the user. Where the user is discharged to home and when his or her condition so requires, community and domiciliary services should be available.
- 5.8 Users have the right to be treated with dignity in relation to their diagnosis, treatment and care, which should be rendered with respect for their culture and values.
- 5.9 Users have the right to enjoy support from family, relatives and friends during the course of care and treatment and to receive spiritual support and guidance at all times.
- 5.10 Users have the right to relief of their suffering according to the current state of knowledge.
- 5.11 Users have the right to humane terminal care and to die in dignity.

6. Rights related to application of the above rights:

- 6.1 The exercise of the above rights implies that appropriate means are established for this purpose.
- 6.2 The enjoyment of these rights shall be secured without discrimination.
- 6.3 In the exercise of these rights, users shall be subjected only to such limitations as are compatible with human rights instruments and in accordance with a procedure prescribed by law.
- 6.4 If users cannot avail themselves of the rights set forth in this document, these rights should be exercised by their legal representative or by a person designated by the user for that purpose; where neither a legal representative nor a personal surrogate has been appointed, other measures for representation of those users should be taken.
- 6.5 Users must have access to such information and advice as will enable them to exercise the rights set forth in this document. Where users feel that their rights have not been respected they should be enabled to lodge a complaint. In addition to recourse to the courts, there should be independent mechanisms at institutional and other levels to facilitate the processes of lodging, mediating and adjudicating complaints. These mechanisms would, inter alia, ensure that information relating to complaints procedures was available to users and that an independent person was available and accessible to them for consultation regarding the most appropriate course of action to take. These mechanisms should further ensure that, where necessary, assistance and advocacy on behalf of the user would be made available. Users have the right to have their complaints examined and dealt with in a thorough, just, effective and prompt way and to be informed about their outcome.

Health Rights of social groups with special health needs or requiring special attention:

It should be emphasised that while defining health rights, and even within the universal health care model, right from the first step, addressing the rights of social groups with special health needs is essential. Establishment of any system of rights is relevant only if it also benefits the most vulnerable or deprived sections of the population, and addresses the special needs of people facing situations where their basic

rights are most likely to be denied. At the same time, adequate health care for various sections with special health needs is unlikely to be achieved without a robust and effective system for universal access to health care being in place. Hence, the argument here is not for a proliferation of targeted or special programmes grafted onto a weak health system. Rather there is a need to integrate special services, along with systemic attitudes of equity, non-discrimination and greater sensitivity, into a much more robust and responsive general health care system. Hence the provisions for universal access to health care need to be implemented especially keeping in view sections with special health needs or requiring special attention. These groups could be broadly classified into three categories (with partial inter se overlaps):

- (a) Groups with special needs on the basis of some biological element/s while being socially conditioned, like, women, children, aged persons.
- (b) Groups facing *special health* challenges, like, persons with psycho-social problems, persons living with HIV-AIDS, persons with disabilities.
- (c) Groups suffering from social exclusion or social marginalisation dalit communities, adivasi communities, displaced people, people in conflict situations, unorganized sector workers, urban deprived communities and sexual minorities.

Some of the issues which need to be taken into account for such a holistic understanding of health rights are very briefly outlined here -

Women's right to health care, including provision of services related to both reproductive and non-reproductive health issues more common among women, along with appropriate general health services for women;

Children's right to health care, with a focus on nutritional supplementation, control of infectious diseases in childhood and reduction in infant and child mortality;

Health rights of HIV-AIDS affected persons, including facilities for detection, counseling, non-discriminatory treatment and access to anti-retroviral drugs;

Right to mental health care, with a focus on strengthening primary mental health care, non-discriminatory and non stigmatized quality treatment and community based rehabilitation systems;

Health rights of persons with disabilities, including both special services (e.g. orthopaedic, ophthalmic, ENT services etc.) required for care and rehabilitation, as well as assured access to general health services by removing barriers to access;

The need to make provisions for preventing discrimination in the health sector against *Dalits and Adivasis* who face traditional social discrimination in myriad forms should also be emphasised here, including



measures for improved socio-economic conditions for these large sections of the people who face have historically suffered reduced access to both healthy living conditions and health care;

Right to health care for unorganised workers, who lack effective health care coverage and face a range of occupational hazards, with a clear liability on employers;

Right to health Care for urban deprived communities, including putting in place urban primary health care systems and effective referral mechanisms;

Health rights in conflict situations, where due to communal or other forms of violence persons from particular communities may be denied access to basic health services or may be discriminated against;

Health rights of communities facing displacement or involuntary resettlement, depriving them of their customary environment and livelihood, and placing them in often hostile new surroundings which may include threats to health and poorer access to health care; and

Health rights of especially vulnerable sections of populations like women forced into commercial sexual exploitation, trafficked persons.

This list may be further elaborated to include the elderly, migrants and other categories of vulnerable people. Given the fact that all these groups together add up to a sizeable majority of the population, the overarching role of an effective general health system should be re-emphasised. Such a system would need to ensure provision of various special services, and to institutionalise protections against various forms of discrimination.

Access Guide to relevant International Instruments:

International treaties

CEDAW Convention on the Elimination of All Forms of Discrimination against Women.

http://www.un.org/womenwatch/daw/cedaw/index

CEDAW the Optional Protocol.

http://www.un.org/womenwatch/daw/cedaw/protocol/text.htm

CEDAW General Recommendations. (See especially Recommendation 25 on health and 19 on violence against women)

http://www.un.org/womenwatch/daw/cedaw/recomm.htm

ICESCR International Covenant on Economic, Social and Cultural Rights.

http://www.ohchr.org/english/law/cescr.htm http://66.36.242.93/treaties/cescr.php

ICESCR General Comments. (See especially Comment 14 on health and 16 on equal rights for women and men)

http://www.ohchr.org/english/bodies/cescr/comments.htm

CERD International Convention on the Elimination of All Forms of Racial Discrimination.

http://www.unhchr.ch/html/menu3/b/d_icerd.htm

CRC Convention on the Rights of the Child.

http://www.unhchr.ch/html/menu3/b/k2crc.htm

CMC. Convention on the Protection of the Rights of All Migrant Workers

http://www.unhchr.ch/html/menu3/b/m_mwctoc.htm

UDHR Universal Declaration of Human Rights.

http://www.unhchr.ch/udhr/

Regional treaties and organizations

Africa

African Charter on Human and Peoples' Rights (1981).

http://www1.umn.edu/humanrts/instree/z1afchar.htm

Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa.

OTHER DESIGNATION OF THE PERSON OF THE PERSO

http://www.achpr.org/english/_info/women_en.html

African Union. http://www.africaunion.

ora/home/Welcome.htm

African Commission on Human Rights.

http://www.achpr.org/english/_info/index_women_en.html

Europe

European Convention on Human Rights (1950).

http://www.hri.org/docs/ECHR50.html

European Social Charter (1961).

http://www1.umn.edu/humanrts/euro/z31escch.html

Council of Europe.

http://www.coe.int/t/e/Human_Rights/

European Court of Human Rights.

http://www.echr.coe.int/echr

EU and Gender Equality.

http://europa.eu.int/comm/employment_social/gender_equality/index_en.html

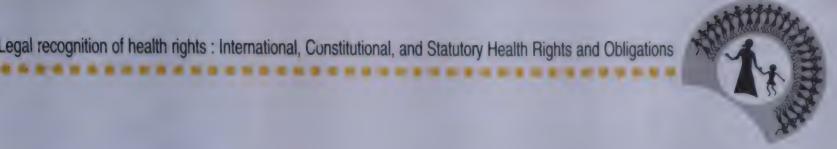
EU and Health.

http://europa.eu.int/comm/health/ph_overview_en.htm

http://www.osce.org/odihr/13371.html

The Americas

American Convention on Human Rights (1969).



http://www.oas.org/juridico/english/Treaties/b-32.htm

Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1988).

http://www.oas.org/juridico/english/Treaties/a-53.htm

Inter-American Convention on the Prevention, Punishment and Eradication of Violence Against Women, 'Convention of Belem do Para' (1994).

http://www.oas.org/cim/English/Convention%20Violence%20Against%20Women.htm Organization of American States.

http://www.oas.org/main/main.asp?sLang=E&sLink= http://www.oas.org/key_issues/eng Inter-American Commission.

http://www.cidh.org/basic.eng.htm Inter-American Court.

http://www.corteidh.or.cr/index_ing.html

Consensus documents

Beijing plus 5 and Beijing Platform for Action.

http://www.un.org/womenwatch/daw/followup/beijing+5.htm

Declaration of Alma Ata (1978).

http://www.phmovement.org/charter/almaata.html

Declaration of Commitment on HIV/AIDS, 'Global Crisis-Global Action' (2001).

http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html

Declaration on the Elimination of Violence against Women (1993).

http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/A.RES.48.104.En?Opendocument

Declaration on the Right to Development (Vienna Declaration and Programme of Action) (1993).

http://www.hri.ca/vien-na+5/vdpa.shtml

Declaration on the Rights of Disabled Persons (1975).

http://www.unhchr.ch/html/menu3/b/72.htm

ICPD Programme of Action (Cairo Programme of Action) Report of the International Conference on Population and Development (1994).

http://www.iisd.ca/linkages/Cairo/program/p00000.html

Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, Maastricht, January 1997.

http://www1.umn.edu/humanrts/instree/Maastrichtguidelines_.html

Millennium Declaration (MDGs) (2000).

http://www.developmentgoals.org

People's Charter for Health.

http://www.phmovement.org/pdf/charter/phm-pch-english.pdf

Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (1991).

http://www.unhchr.ch/html/menu3/b/68.htm

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Review Questions:

- 1. What is the meaning of a legal right to health?
- 2. What are the main sources of health rights?
- 3. To what extent do international covenants and declarations help the Indian citizen in the area of health rights.
- 4. What are normative contents of right to health?
- 5. What are the main obligations of governments related to right to health?
- 6. Enumerate some commonly recognized health rights.

Application Question:

- Discuss the health rights that are pertinent to violations that are commonly suffered by persons with HIV/ AIDS in India and the rights that must be recognized to address them.
- 2. To treat unequals equally is discriminatory. Unequals must be treated unequally. What would be the

implications of this legal principle in a district health plan? Review the NRHM and identify the health related rights that it satisfies and those it does not satisfy.

Project Work:

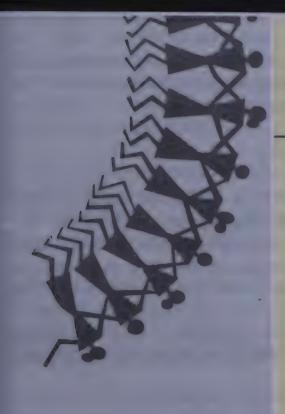
- 1. How are the State's obligations to respect, protect, fulfill health rights reflected in a district health plan in your state? How would you modify elements of the district plan to bring it more in consonance with these obligations? (Please note: not to go only by the text of the NRHM district plan, but to also take into account all that is happening in the district under the state funds and in the course of routine administration and functioning- even if these have not been captured in the written text of the district plan).
- 2. Health care users have a number of health rights and these have been listed in the chapter. How would the annual plan of the rogi kayan samiti of a district hospital or a peripheral PHC be made consistent with ensuring that users enjoy these rights?

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Lesson THREE

Professionals Regulation of Health Care Services & Providers

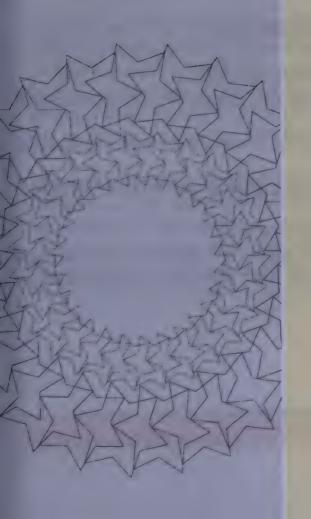


In this lesson we shall discuss:

The role of professional bodies in professional regulation – Modern Medicine, Indian Systems of Medicine and Homeopathy including relevant court judgements

The responsibility of registration authorities

Some of the issues faced by professional councils – Education & Human Resource



INTRODUCTION

Education, training and practice in medical, paramedical and Indian systems of medicine in India are governed by various central and state legislations. The prominent central legislations are- The Indian Medical Council Act 1956, The Dentists Act 1948, The Pharmacy Act 1948, The AICTE Act, 1987, The Indian Nursing Council Act of 1947, The Indian Medicine Central Council Act 1970 and The Homeopathy Central Council Act 1973. These acts have led to the creation of the quasi governmental bodies called the councils who were entrusted with the registration /licensing of professionals.

HOW DOES A PROFESSIONAL GET LICENSE TO PRACTICE?

Personal licensing is the process by which legal permission is granted by a competent, usually public, authority to an individual to engage in a practice or an activity that is otherwise unlawful. Licensing is thus mandatory. A license is usually granted on the basis of examination or proof of education, or both, rather than on measurement of actual performance. The agency, by issuing a license, certifies that those licensed have attained the minimal degree of competency necessary to ensure reasonable protection of public health, safety, and welfare. A license is usually permanent but may be conditional on annual payment of a fee, proof of continuing education, or proof of competence. Grounds for revocation of a license usually include incompetence, commission of a crime (whether or not related to the licensed practice) or immoral behaviour.

Personal licensing practices vary from one region of the world to another. In India standards are set nationally by the councils, but the states do the licensing for doctors. Nurses and other allied professionals area also registered in similar ways. The national councils are empowered to make periodic inspections and review the functioning of Medical / Dental / Nursing / Pharmacy institutions in the states.

WHAT ARE THE RESPONSIBILITIES OF LICENSING AUTHORITIES?

The scope of responsibilities of licensing agencies involves the following activities:

- Examination of the applicant's credentials to determine whether their education, experience, and moral fitness meet statutory or administrative requirements
- Administration of examinations to test the academic and practical qualifications of medical graduates against preset standards
- Granting of licenses on the basis of reciprocity or endorsement to applicants from other localities or foreign countries
- Issuance of regulations establishing professional standards of practice
- Investigation of charges of violation of standards established by statute and regulation; suspension
 or revocation of violators' licenses; and restoration of licenses after a period of suspension or
 further investigation.



Professional regulation in India

The Indian Medical Council Act 1956, was enacted primarily for the reconstitution of the Medical Council of India, the maintenance of an all India Register for professionals and for related matters.

The Act confers upon the Medical Council powers to grant recognition of medical qualifications, maintenance of an all India register (a public document) which contains the names of medical practitioners possessing medical qualifications recognized by the Council, lay down minimum standards of education and for prescribing standards of professional conduct, etiquette and code of ethics.

The council sets down the broad principles and minimum requirements, and the details are left to the universities and colleges. On completion of the MBBS degree the state council will award registration. The universities to which the medical colleges are affiliated, are only responsible for conducting the examinations and award of degrees.

For continuing medical education (CME) the National Academy of Medical Sciences created the National Board of Examinations, which is now under the control of the Ministry of Health, as an independent examining body. The Medical Council of India has also set up a CME cell to organize CME activities with support from non-resident Indian doctors. Continuing medical education is still not mandatory.

Section 24 of the Medical Council Act empowers the council to direct the removal of the name of any person enrolled on a State Medical Register on the ground of professional misconduct. However these powers are not clear and in practice they are never used. In many countries the Medical Council is a body that also serves for the protection of the interests of the persons who may have suffered on account of any negligence or deficiency in the service rendered by members of the medical profession.

The Dentists Act 1948 was also formulated to regulate dental education, dental professionals and dental ethics and also to make recommendations to the government for granting permission to start college / increase seats in college. The council is empowered to inspect the dental colleges for review. The council also gives details of regulations regarding dental hygienists and dental mechanics. The details are available at: http://www.dciindia.org/dci/index.aspx. The BDS syllabus is currently revised and the new programme will be of 5 years duration with the internship integrated into the course.

The Indian Nursing Council Act of 1947 was enacted to provide for the constitution of the Central Nursing Council and lay down uniform educational standards in education and practice. The Council is also responsible for the regulation of courses including thee Degree program, Diploma programs, Certificate courses in Nursing & Midwifery, ANMs, and Health Visitors. One of the major lacunae in the Act is that it does not contain provisions either to stop unqualified non-registered nurses in the private nursing homes from practicing or to de-register nurses who violate its code of guidelines.

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According to the Macroeconomics report only an estimated 40% of registered nurses are active in their profession because of low recruitment, migration, attrition and drop-outs due to poor working conditions. Profession because of low recruitment, migration, attrition and drop-outs due to poor working conditions. Most nurses in service are diploma holders and some are graduates. There are no specialist nurses in clinical areas such as Clinical Nurse Specialist (CNS), Nurse Practitioner (NP), Nurse Anaesthetist or Midwife in India.

Unlike with the medical council, de-recognition by the Indian Nursing Council has less impact as they continue to function with the permission of the State Nursing Council.

The Pharmacy Act of 1948 was enacted to regulate the profession (Practice & Education) of Pharmacy in India. The Council, recognizes not only courses starting from a undergraduate level, but also a Diploma course in Pharmacy. Consequent to the implementation of the AICTE Act, 1987 the Pharmacy institutions in India are under the purview of an additional statutory body namely AICTE besides the existing statutory body of PCI.

The Indian Medicine Central Council Act, 1970 was enacted primarily to lay down minimum standards for education and practice of Indian Systems of Medicine, i.e. Ayurveda, Unani, and Siddha. Prior to the enactment, the training in these fields were mostly without a formal method. The Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) was established as Department of Indian Systems of Medicines and Homoeopathy (ISM & H) in Ministry of Health & Family Welfare in March, 1995 and was renamed as Department of AYUSH in November, 2003. A national level institute for Indian Systems of Medicine is also coming up.

The Homeopathy Central Council Act, 1973 was enacted primarily to regulate the conduct of Homeopathic practitioners in India.

Summary:

Education, training and practice in medical, paramedical and Indian systems of medicine in India are governed by various councils at the central and state levels. These councils primarily act as bodies conferring recognition of professional educational institutions in their domain. They do not act effectively as regulatory mechanism of the profession and have little role in the area of health rights. The councils do not assure standards of care beyond graduation.

Even on medical education, it is not proactive in promoting policies that serve underserviced areas or introduce innovation. They do not have a live database of functional professionals.

The Commission on macroeconomics and health recommended that the Government initiates action to open up the membership of these bodies to civil society and non-medical persons, provide them financial support to discharge their functions in a professional manner, develop and maintain databases of doctors who are licensed/have gone abroad, organize CME and re-certification programmes, and design vigilance procedures for those who have been de-licensed for malpractice.



What are the implications of self regulation?

Self regulation is a very useful regulatory instrument which allows a group of professionals or providers to set standards for its members' behaviour. Self regulatory arrangements vary considerably in terms of the degree of governmental oversight. The arrangement, however, has its own advantages and disadvantages. The potential advantages are high commitment to rules, well-informed rule making, low costs to government, close fit of regulatory standards with those seen as reasonable by actors, potential for rapid adjustment, enforcement potentially more effective, and a potential for combining with external oversight. And the disadvantages are that it could be self serving, an impetus towards monopolistic behaviour, excludes public from rule-making procedures, there could be laxness of enforcement towards providers, public distrust of enforcers, problematic legal oversight, and public preference for governmental responsibility.

Cross-Practice:

One of the issues of professional regulation relates to cross –practice- can doctors trained in one discipline practice another?

In *Poonam Verma V.Ashwin Patel & others* Supreme Court addressed the issue of a Homeopathic doctor prescribing an Allopathic medicine. The Hon'ble Supreme court stated that it is unacceptable that a person having studied one system of medicine could claim to treat the patient by drugs of another system of medicine which he has not studied. The person was hence liable to be prosecuted under section 15 (3) of the Indian medical Council Act of 1956. There are other rulings now that have reversed it. But this needs to be asceratained.

This is importance in the context of NRHM. What are the implications for mainstreaming AYUSH and in training ayush doctors to play roles that hitherto only modern medicine practitioners have been doing. In practice AYUSH doctors are advised to keep to providing AYUSH drugs only and trained to give modern medicines to the level of a paramedical or nursing staff.

Emerging HR legal issues under NRHM:

There are a growing number of areas where legal questions arise- for example: Can ASHAs prescribe antibiotics? Can they be trained to prescribe antibiotics? Can nurse practitioners be allowed? Can medical graduates be skilled to play specialist roles- like emergency obstetric care?

Though there is no clear resolution on these issues- the following guidelines help:

- a) Those trained to deliver a particular function can be allowed to perform that function- provided there is a clear certifying mechanism in place.
- b) However the above does not apply to creating a doctor, a nurse or a pharmacist- where only their passing the examination of a recognized educational institution makes them eligible.

The code of ethics

The code of ethics specifies the duties of Physician / Dentist / Nurse / Pharmacist towards their patients, fellow professionals and to the society. The State Councils are empowered by their respective legislations to formulate guidelines / code of ethics to be applicable to all the institutions under its jurisdiction. The individual code of ethics can be accessed at the respective council websites.

Redressal mechanism

All the councils (National / State / District) offer redressal mechanisms. Aggrieved persons can approach the councils for necessary action. The procedure for seeking redressal from Medical council is available at http://www.mciindia.org/tools/grievances/index.htm. At the district level, the Chief Medical Officer of the district is the concerned officer. Before a complaint is made to the state council is made, the district medical officer may be approached.

Professional associations

The Professional associations were to be an important institution for promoting a self regulatory approach. To a large extent the medical councils and other professional councils are also self –regulatory bodies as their composition is made up exclusively of professionals from the same stream. However the lack of public participation has been a problem. The greater problem is that the when the obligations and accountability for the provision of health is with the government – but if regulation of the main health care providers is not with it – could it fulfil its obligations? Similarly what part of the obligations of health care provision and achievement of public health goals are the councils willing to own upto.

Which are the active professional associations in India?

The Indian Medical Association (IMA), the national organization of "Doctors of Modern Scientific System of Medicine", was organized in 1928, and Before the establishment of the Indian Medical Association, some of the members of the profession were members of the British Medical Association, which then had some branches in the-then Undivided India. After the Indian Medical Association was organized, an agreement was struck between both the Associations, and an understanding was reached that the British Medical Association will not have any branch in India, and both the Associations got mutually affiliated – a relationship which still continues till date.

The All India Dental Association became IDA in 1946. For the past 60 years, the IDA has been the leading authority in the Indian oral health sector. The IDA have innovated ways to communicate with the public and the government. The IDA remains unchallenged in its efforts to promote oral health through education, patient awareness and advocacy work across the country.



The TNAI(Trained Nurses Association of India) is a professional association for the nurses in India. It is a registered society under the societies registration act of 1860. The association has established within its jurisdiction the following organisations:

- health visitors' league (1922)
- midwives and auxiliary nurse-midwives association (1925)
- student nurses association (1929-30)

The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of pharmacy. The IPA is committed to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and others on vital professional issues and support pharmaceutical education and sciences in all aspects.

The involvement of professional associations in the establishment of licensure, certification, and accreditation standards is an important aspect of quality assurance in all health systems. However, some studies have held that the professional associations organized by health providers tend to act more as self-interested trade guilds rather than as credible organizations for self-regulation. Much of the professional regulatory functions in India have been delegated to the quasi-governmental agencies such as the councils at the national and state levels and these do not have sufficient public or even government participation or accountability.

Review Questions:

- How does a professional get a license to practice?
- 2. What are the responsibilities of professional councils?

Application Question:

 What are the implications of Supreme court decision in the case Poonam Verma Vs. Ashwin Patel & others

Project Work:

1. The Indian Dental Association has been observed to be authenticating certain products (Colgate toothpaste) in the market. Can this be justified?



Lesson FOUR

Right to Information



In this lesson we shall discuss:

Significance of right to information

Meaning of right to information under the Right to Information Act, 2005

Obligations of public authorities towards disclosure of information

Process for obtaining information under the RTI Act

The time limit to get the information under the RTI Act

The requirement of payment of fee under the RTI Act

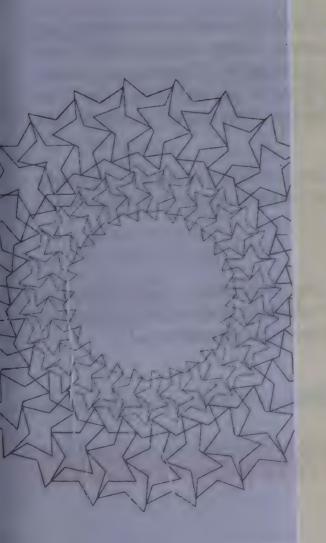
Obligations for access to and dissemination of information

Information which is exempt from disclosure

Grievance redressal mechanism under the RTI Act

How the RTI Act can be used to improve health care services

Jan sunwais, social audits



Public Health Resource Network

INTRODUCTION:

Till about 10 years back, Indian law tilted heavily towards non-disclosure of official information under the shroud of secrecy legitimized by the colonial Official Secrets Act of 1889, amended in 1923. This Act prohibited disclosure of non-classified information also, apart from information related to security of the State, sovereignty of the country and friendly relations with foreign states. This colonial regime of secrecy was supported by the Civil Service Conduct Rules and the Indian Evidence Act which gave further sanctions to government officials to with-hold information from public.

The only recognition of right to information was in judicial rulings of Indian constitutional courts that subsumed this right under fundamental right to freedom of speech and expression (Article 19 of constitution) or fundamental right to life and liberty (Article 21 of Constitution). For instance, the Supreme Court's landmark judgment in State of U.P. v. Raj Narain AIR 1975 SC 865 6, held that "the people...have a right to know every public act, everything that is done in a public way, by their public functionaries". However this meant that for every case, the doors of courts would have to be knocked, which was not only cumbersome but also an uncertain route to this vital right.

Formal legal recognition of right to information through domestic laws started happening in India only in the last decade when many states passed their own right to information laws. The central government passed the Right to Information Act in year 2005. This Act not only relaxed several restrictions on information disclosure and created enabling structures have now been created where by which information could become public resource. Governments have now been obliged to come forward on their own and proactively share it.

SIGNIFICANCE OF RIGHT TO INFORMATION:

If there is one right that must be seen as the gateway for access to all the basic human entitlements such as health, food, livelihood, shelter, personal safety and security, justice, healthy environment, even basic infrastructure like roads, transport, electricity, it is the 'Right to Information'. Whether it is workers fighting for fair employment terms, or women who want equality, or disabled persons who strive to be mainstreamed, or displaced who seek relief and rehabilitation, access to information is crucial to take their struggle for these rights forward.

Potentially the most important transformation that the right to information could bring about is in improving governance. Right to Information is an extremely powerful weapon in the hands of people, in three principal ways:

One, the people can seek information to unveil corruption and inefficiency, discrimination or arbitrariness in the function of government bodies and instrumentalities, and in turn this makes it more likely for such decisions to be challenged and changed, account for and/ or act.

¹ For instance: Tamil Nadu (1997); Goa (1997); Rajasthan (2000); Karnataka (2000); Delhi (2001); Maharashtra (2002); Madhya Pradesh (2003); Assam (2002) and Jammu and Kashmir (2004).



- > Two, even without the citizen seeking any specific information, the public authorities and public processes undergo a greater transparency and fair play under the constant fear of being found out and challenged. The authority loses the halo of being privileged by virtue of his position to act according to his or her own will or pleasure and becomes obliged to act according to norms and be accountable to the persons he serves.
- Three, right to information as postulated in the Indian law, obliges the state to *suo-moto* (on its own) and proactively disseminate all such information which is vital to the citizens' lives and well-being. This too lends a big hand to the process of demystification of state apparatus and opening up of the sacrosanct envelope of "Official Secrets", to spill its long-hidden contents into public domain. These three parallel forces, working together, hold the promise of contributing to reducing the gap between the rhetoric and reality of democracy.

SALIENT FEATURES OF THE RIGHT TO INFORMATION ACT (RTI ACT), 20052:

The RTI Act describes itself as a law to provide for setting out the practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, the constitution of a Central Information Commission and State Information Commissions and for related matters.

Right to Information is the right to access information that is in the hands of (i.e., "held by or under the control of") 'any public authority'.

WHAT IS THE MEANING OF INFORMATION UNDER THIS ACT?

Information that is in the hands of (i.e. held by or under the control of) any public authority in any form, including:

- records (any document, manuscript and file; any microfilm, microfiche and facsimile copy of a document; any reproduction of image or images embodied in such microfilm (whether enlarged or not); and any other material produced by a computer or any other device)
- documents
- memos
- e-mails
- · opinions, advices
- press releases
- · circulars, orders
- logbooks
- contracts
- reports

² Full text of the Act is available at: http://persmin.nic.in/RTI/RTI-Act.pdf



- papers
- samples
- models
- data material held in any electronic form and
- information relating to any private body which can be accessed by a public authority under any other law for the time being in force

Further, under the Act, right to information of the above kinds has been clearly defined to mean the right of every citizen vis-à-vis every 'public authority' (see below for definition of public authority) to:

- inspect the work, documents, records of the public authority (e.g., to inspect any public development work that may be still under construction or completed and the relevant records etc.):
- take notes, extracts or certified copies of documents or records of the public authority;
- take certified samples of relevant materials (e.g., samples of material used in the construction of roads, drains, buildings etc);
- obtain information in the form of diskettes, floppies, tapes, video cassettes or in any other electronic mode or through printouts where such information is stored in a computer or in any other device.

Finally, any person can demand to be told the status of his/ her requests or complaints regarding any particular information sought by him/ her.

WHO ARE PUBLIC AUTHORITIES UNDER THIS ACT?

First of all, it is important to know that the RTI Act defines the term "public authority" very expansively, to mean - any authority or body or institution of self-government (including Panchayati Raj Institutions) constituted, owned, controlled or substantially financed by funds provided directly or indirectly by central or state government. Interestingly, under the RTI Act the term public authority also includes Non-Government Organizations (NGOs) which are substantially financed, directly or indirectly by funds provided by the government. This means that all the bodies, including private bodies, that come under the above definition shall be responsible for all the obligations mentioned under the Act, including the sharing of all their information as listed out above. Also, even for private bodies that are not covered within the Act's ambit directly, if their information can be accessed under any other law in force by a public authority, such information can also be requested for from such public authority. In a landmark decision of 30-Nov-2006 ('Sarbajit Roy versus DERC') the Central Information Commission also reaffirmed that privatised public utility companies continue to be within the RTI Act, their privatisation notwithstanding.



Exclusion of some specified offices and organisations: Central Intelligence and Security agencies specified in the Second Schedule of the Act like IB, RAW, Directorate of Revenue Intelligence, Central Economic Intelligence Bureau, Directorate of Enforcement, Narcotics Control Bureau, Aviation Research Centre, Special Frontier Force, BSF, CRPF, ITBP, CISF, NSG, Assam Rifles, Special Service Bureau, Special Branch (CID), Andaman and Nicobar, The Crime Branch-CID-CB, Dadra and Nagar Haveli and Special Branch, Lakshadweep Police. Agencies specified by the State Governments through a Notification will also be excluded.

The exclusion however, is not absolute and these organizations have an obligation to provide information pertaining to allegations of corruption and human rights violations. Such information relating to allegations of human rights violation could be given to a citizen but only with the approval of the Central or State Information Commission.

Obligations. of Public Authority under this Act.

It is the duty of public bodies to proactively disclose information suo moto (on their own). The law clearly states that every public authority must on its own, provide as much information to the public, at regular intervals through various means of communications, including internet, so that the public have minimum resort to the use of this Act to obtain information. Further, every information must be disseminated widely and in such form and manner which is easily accessible to the public, taking into consideration the cost effectiveness, local language and the most effective method of communication in that local area, and free of cost or at minimum prescribed cost.

The other obligation is to respond to requests for information. To enable this the public authority has to put in place a system which specifies the process of a citizen seeking information, a time period by which it is provided and mechanisms to redress grievances and penalize those not adhering to the obligations under this act.

What Information should be displayed?

Information to be displayed would include issues concerning projects that directly affect the people or the environment, information on health, agriculture, weather conditions, or simply, information about the services provided or the functions performed by various public bodies.

For example, if a health facility is being constructed for an area – the affected people of that area shall have the right to know from the government, without asking, all the details regarding the project including information regarding the scale and cost of the project, the blueprint, time frame for completion, information regarding the contractor undertaking the construction and process of selection of the contractor and other professionals, materials used in construction, kinds and nature of services that would be made available there, the number of staff that would man the facility and

their qualifications. This type of information must be made known publicly by the concerned government office/ department to all citizens, without waiting for each citizen to approach the concerned department individually.

WHAT ESSENTIAL PROCESSES MUST BE PUT IN PLACE TO FULFIL OBLIGATIONS OF PUBLIC AUTHORITIES UNDER THE ACT?:

- Maintaining records duly catalogued and indexed in a manner and the form which facilitates the
 right to information under this Act and ensure that all records that are appropriate to be computerised
 are, within a reasonable time and subject to availability of resources, computerised and connected
 through a network all over the country on different systems so that access to such records is
 facilitated.
- Publishing and disseminating all the required information³ in effective ways.

(A template of information handbook that is required to be maintained by every public authority is available at http://persmin.nic.in/RTI/RTI-Templates.pdf)

Designating their Public Information Officers (PIO) and Assistant Public Information Officers
(APIOs) called as Central PIO/ APIO or State PIO/ APIO depending on whether the concerned
government is central or state government.

³ The information required to made available by every public authority includes atleast the following: particulars of its organisation, functions and duties; the powers and duties of its officers and employees; the procedure followed in the decision making process, including channels of supervision and accountability; the norms set by it for the discharge of its functions; the rules, regulations, instructions, manuals and records, held by it or under its control or used by its employees for discharging its functions; a statement of the categories of documents that are held by it or under its control; the particulars of any arrangement that exists for consultation with, or representation by, the members of the public in relation to the formulation of its policy or implementation thereof; a statement of the boards, councils, committees and other bodies consisting of two or more persons constituted as its part or for the purpose of its advice, and as to whether meetings of those boards, councils, committees and other bodies are open to the public, or the minutes of such meetings are accessible for public; a directory of its officers and employees; the monthly remuneration received by each of its officers and employees, including the system of compensation as provided in its regulations; the budget allocated to each of its agency, indicating the particulars of all plans, proposed expenditures and reports on disbursements made; the manner of execution of subsidy programmes, including the amounts allocated and the details of beneficiaries of such programmes; particulars of recipients of concessions, permits or authorisations granted by it; details in respect of the information, available to or held by it, reduced in an electronic form; the particulars of facilities available to citizens for obtaining information, including the working hours of a library or reading room, if maintained for public use; the names, designations and other particulars of the Public Information Officers; such other information as may be prescribed and thereafter update these publications every year; all relevant facts while formulating important policies or announcing the decisions which affect public; reasons for its administrative or quasi-judicial decisions to affected persons.



- the Central Public Information Officer or State Public Information Officer, as the case may be, on receipt of a request under section 6 shall, as expeditiously as possible, and in any case within thirty days of the receipt of the request, either provide the information on payment of such fee as may be prescribed or reject the request for any of the reasons specified in sections 8 and 9.
- Where such request cannot be made in writing, the Central Public Information Officer or State
 Public Information Officer, as the case may be, shall render all reasonable assistance to the
 person making the request orally to reduce the same in writing.
- Where a request has been rejected under sub-section (1), the Central Public Information Officer
 or State Public Information Officer, as the case may be, shall communicate to the person making
 the request:
 - o the reasons for such rejection;
 - o the period within which an appeal against such rejection may be preferred; and
 - o the particulars of the appellate authority.
- If allowing partial access, the PIO shall give a notice to the applicant, informing:
 - o that only part of the record requested, after severance of the record containing information which is exempt from disclosure, is being provided;
 - o the reasons for the decision, including any findings on any material question of fact, referring to the material on which those findings were based;
 - o the name and designation of the person giving the decision;
 - o the details of the fees calculated by him or her and the amount of fee which the applicant is required to deposit; and
 - o his or her rights with respect to review of the decision regarding non-disclosure of part of the information, the amount of fee charged or the form of access provided.
- Any information relating to any occurrence, event or matter which has taken place, occurred or happened twenty years before the date on which any request is made under section 6 shall be provided to any person making a request.
- Where the information sought for does not lie within the domain of a particular department, it the responsibility of the PIO or APIO of that public authority to ensure that the information is obtained from the appropriate department or section.
- If the information requested for is held by or its subject matter is closely connected with the function of another public authority (in whole or part), it is the PIO's responsibility to transfer/ forward the application or concerned portions of the application to a PIO of the other public authority

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within 5 days and inform the applicant immediately. In addition, every public authority is required to designate a person to receive RTI requests and appeals for forwarding to the PIOs.

If information sought has been supplied by third party or is treated as confidential by that third
party, the PIO shall give a written notice to the third party within 5 days from the receipt of the
request and take its representation into consideration, and the third party must be given a chance
to make a representation before the PIO within 10 days from the date of receipt of such notice.

The only grounds for rejection of an application can be:

- 1. If the information sought for is covered by exemption from disclosure (under S.8);
- 2. If providing the information sought for infringes copyright of any person other than the State. (S.9)

PROCESS FOR OBTAINING INFORMATION UNDER THE RTI ACT:

The process for submitting application for information is very simple, basically two-step:

1. Apply in writing or through electronic means, in Hindi or English or the official language of the area, to the PIO (or APIO), specifying the particulars of the information sought

Any reason for seeking the particular information is not required to be given.

2. Pay fees as may be prescribed (if not belonging to the below poverty line category) - see below.

WHAT IS THE TIME LIMIT TO GET THE INFORMATION UNDER THE RTI ACT?

- 1. 48 hours for any information that concerns the life and liberty of a person
- 2. 30 days from the date of application
- 3. **35 days** (5 days shall be added), in case the application for information is given to Assistant Public Information Officer.
- 4. If the PIO transfers the request to some other public authority that is better concerned with the information requested), the time allowed to reply is **30 days** but computed from the day after it is received by the PIO of the transferee authority, provided that the transfer of application is made to the transferee PIO within 5 days by the transferor PIO.
- 5. If the interests of a third party are involved (information sought for relates to or has been supplied by a third party and has been treated as confidential by that third party) then time limit will be 40 days (maximum period + 10 days time given to the third party to revert).



- 6. Information about human rights violations by Security agencies is to be provided within 45 days, subject to prior approval of the Central Information Commission.
 - Failure to provide information within the specified period is a deemed to be refusal on part of the authority to provide the requested information, for which the authority becomes liable.
 - ➤ If a PIO fails to furnish the information asked for under the Act or fails to communicate the rejection order, within the time specified, the PIO shall be liable to pay a penalty of Rs 250 per day for each day of delay, subject to a maximum of Rs 25,000 And may also face disciplinary action within the organization.

WHAT IS THE REQUIREMENT OF PAYMENT OF FEE?

1. The prescribed application fees, which must be reasonable:

For Central government related public authorities, as of 2006, there is a fee of Rs. 10 for filing the request, Rs. 2 per page of information in A4 or A3 size paper (and actual cost for copies of larger size paper) created or copied; actual cost for samples or models; for information in floppies or disks Rs. 50 per floppy/ disk; for information provided in printed form, the price of the publication or Rs. 2 per page for photocopy of extracts from publication; for inspections, Rs. 5 for 15 minutes of inspection after the first hour. States fix their own rules.

2. If further fees are required, then the same must be intimated in writing, with calculation of the details of how the figure was arrived at;

Whenever Triveni would go to her ration shopkeeper, he would always say "No stock". She never got her rice entitlements for several months. She was given only 10 litres of kerosene against her entitlement of 14 litres and she would get only 10-15 Kgs of wheat against her entitlement of 25 Kgs. The wheat was given to her at Rs 5 per Kg, whereas the official price is Rs 2 per Kg.

Triveni applied under the RTI Act and asked for official records of rations issued to her and also copies of cash memos purported to have been issued to her. To her utter surprise, she was told that she had been issued 25 Kgs of wheat @ Rs 2 per Kg, 14 litres of kerosene and 10 Kgs of rice every month for more than a year. The cash memos showed thumb impressions having been made in her name, whereas she always signed her signature. Naturally, the thumb impressions were found to be fakes and this showed that the ration dealer had been drawing her ration by faking her thumb impressions for several months.

Triveni has since filed complaints to higher authorities, and what's more she has started getting the proper amounts of rations at the right price.

Arvind Kejriwal, Parivartan documents, 2003

- 3. Applicant can seek review of the decision on fees charged by the PIO by applying to the appropriate Appellate Authority;
- 4. No fees will be charged from people living below the poverty line;
- 5. Applicant must be provided information free of cost if the PIO fails to comply with the prescribed time limit.

OBLIGATIONS FOR ACCESS TO AND DISSEMINATION OF INFORMATION:

- The Act repeatedly imposes the duty on PIOs to disseminate every information in the widest possible manner and form, which are easily accessible to the public.
- PIO must provide information in the form in which it is sought unless it would disproportionately divert the resources of the Public Authority or would be detrimental to the safety or preservation of the record in question, and through various means of communications, including notice boards, newspapers, public announcements, media broadcasts, the internet or any other means, including providing opportunities for inspection of offices of any public authority, so that the public have minimum resort to the use of this Act to obtain information.
- All materials must be disseminated taking into consideration the cost effectiveness, local language and the most effective method of communication in that local area, to the extent possible in electronic format, available free or at such cost of the medium or the print cost price as may be prescribed.

Information which is exempt from disclosure:

The following kinds of information are exempt from disclosure:

- information, disclosure of which would prejudicially affect the sovereignty and integrity of India, the security, strategic, scientific or economic interests of the State, relation with foreign State or lead to incitement of an offence:
- information which has been expressly forbidden to be published by any court of law or tribunal or the disclosure of which may constitute contempt of court;
- information, the disclosure of which would cause a breach of privilege of Parliament or the State Legislature:
- information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information;
- information available to a person in his fiduciary relationship, unless the competent authority is



satisfied that the larger public interest warrants the disclosure of such information;

- information received in confidence from foreign Government;
- information, the disclosure of which would endanger the life or physical safety of any person or identify the source of information or assistance given in confidence for law enforcement or security purposes;
- information which would impede the process of investigation or apprehension or prosecution of offenders;
- cabinet papers including records of deliberations of the Council of Ministers, Secretaries and other officers;
- information which relates to personal information the disclosure of which has no relationship to any public activity or interest, or which would cause unwarranted invasion of the privacy of the individual (but it is also provided that the information which cannot be denied to the Parliament or a State Legislature shall not be denied by this exemption);

Notwithstanding any of the exemptions listed above, a public authority may allow access to information, if public interest in disclosure outweighs the harm to the protected interests.

The Act also allows those part(s) of the record which are not exempt from disclosure and which can reasonably be severed from every part that contains exempt information to be provided.

GRIEVANCE REDRESSAL MECHANISM UNDER THE RTI ACT:

The Act has set up Central Information Commission or State Information Commission, which are empowered to receive and inquire into a complaint from any person, regarding the application for information.

Where a person has a grievance regarding his/ her application under the RTI Act, such person can appeal to a person senior to the PIO in the relevant public authority within 30 days and if still not satisfied he/ she can approach the relevant Information Commission within 90 days of the decision of such senior officer.

Who can complain?

Any person can lodge a complaint regarding any of the following:

(a) If he/she has been unable to submit a request to a PIO/ APIO either because no such officer has been appointed for the concerned public authority, or because the PIO/ APIO has refused to accept the application for information or appeal under this Act

- (b) If he/she has been refused access to any information requested under this Act
- (c) If he/she has not been given a response to a request for information or access to information within the time limit specified under this Act
- (d) If he/ she has been required to pay an excess amount of fee or a fee which he or she considers unreasonable
- (e) If he/ she believes that he/she has been given incomplete, misleading or false information under this Act and
- (f) In respect of any other matter relating to requesting or obtaining access to records under this Act.

How is the complaint regarding information disclose or non-disclosure dealt with?

- Where the Information Commission is satisfied that there are reasonable grounds to inquire into the matter, it may initiate an inquiry in respect thereof.
- The Information Commission while inquiring into any matter under this section, have the same
 powers as are vested in a civil court while trying a suit under the Code of Civil Procedure, 1908,
 and there it may require the public authority to take any such steps as may be necessary to
 secure compliance with the provisions of this Act, including
 - o by providing access to information, if so requested, in a particular form
 - o by appointing a PIO
 - o by publishing certain information or categories of information
 - o by making necessary changes to its practices in relation to the maintenance, management and destruction of records
 - o by enhancing the provision of training on the right to information for its officials
 - o by providing it with an annual report in compliance with clause (b) of sub-section (1) of section 4
 - o require the public authority to compensate the complainant for any loss or other detriment suffered



o impose any of the penalties provided under this Act

Where the Information Commission, at the time of deciding any complaint or appeal is of the opinion that the PIO has, without any reasonable cause, refused to receive an application for information or has not furnished information within time or malafidely denied the request for information or knowingly given incorrect, incomplete or misleading information or destroyed information which was the subject of the request or obstructed in any manner in furnishing the information, it shall impose a **penalty of Rs. 250 per day** (two hundred and fifty rupees each day) till application is received or information is furnished, the total amount of such penalty not exceeding twenty-five thousand rupees; it may further recommend disciplinary action to be taken against such PIO under the applicable service rules.

Sample Application Form under Right to Information Act, 2005

(Separate form to be filled up for each query)

To
The Public Information Officer/ Asstt. Public Information Officer,
(Name & address of public authority)

- 1(a) Name and Address of the Applicant:
 - (b) E-mail address:
 - (c) Phone/Fax. No.
- 2. Subject Matter:
- 3. Details of Information requested:
- (a) Concerned Office/Department:
- (b) Particulars of information required:
- (c) Details of information required:
- (d) Period for which information asked for:
- (e) Any other relevant detail:
- 4. The information can be furnished within 30 days as prescribed under Section 6 (1)/ the information sought for concerns my life and liberty, therefore the information may be furnished to me within 48 hours (Please delete the inapplicable portion).
- 5.(a) Fee enclosed (in cash/DD/Banker's cheque):

(b) The applicant is not liable to pay any fee because he/she is below the poverty line (proof is attached).

(Please tick the applicable option)

- 6. How the applicant would like his information to be sent
- (a) By post
- (b) To be collected by hand
- (c) By e- mail
- (d) By fax

(Please tick the applicable option)

(Name & Signature)

Place: Date:

RTI gets quack pack up By Parivartan

Published in Indian Express, Delhi in August 2004:

Dr Irshad Khan sits in a small room in New Seemapuri in Delhi that is his clinic, attending to a stream of coughing and wheezing patients. He holds a Bachelor's degree in Unani Medicine and Surgery (BUMS). But he has also opened an information counter to spread awareness about people's rights.

Behind this mission was a fight he waged to make a quack flee the area. "Still there are dozens of quacks operating here and I will try to keep fighting against them," he says, recalling how it all began when he started getting patients from Mumtaz Clinic in the area.

The doctor running the clinic, Shahbaz Alam, claimed to be a Unani doctor but was dispensing even allopathic medicines, he alleged. Khan was in a dilemma. He was angry that patients were being taken for a ride but didn't wish to convey an impression that there was any jealousy involved. "So, I filed all the complaints in my brother Naushad Ahmed's name," he said.

He went to the police but was rebuffed. He then sent a letter to the Directorate of Health Services on August 8 last year. Over the next three months, he said, the officials gave one excuse after another for not taking action.

His neighbour, Rajiv Sharma, a member of Parivartan, introduced him to RTI Act. Khan filed an application under RTI Act and received a letter from the Directorate in March, well after the prescribed 30-day period.

They had found that Dr Alam held a Diploma in Unani Medicine and was registered with the Bharatiya Chikitsa Parishad, UP, but not in Delhi. A medical practitioner can practise in Delhi only after registering with medical bodies like Delhi Medical Council for allopathic doctors and Bharatiya Chikitsa Parishad for Unani and Ayurvedic. "The fact that he was not registered means he is a quack," said Dr Anil Bansal, former president of Delhi Medical Association. "Besides nobody can start practising after just a diploma."

Perhaps, warned by the inquiry, the quack packed his bags and left just a week after Dr Khan received the letter.

(http://www.parivartan.com/story.asp?id=71)

RTI AND HEALTH CARE SERVICES:

What the NRHM says about public accountability, RTI and Public Hearings

The NRHM proposes an intensive accountability framework through a three pronged process of community based monitoring, external surveys and stringent internal monitoring (using the health management information system -HMIS).

The Mission Steering Group and the Empowered Programme Committee at the Central and the State level will also monitor progress periodically. The NRHM is committed to publication of Public Reports on Health at the State and the district levels to report to the community at large on progress made. The Planning Commission will also carry out periodic monitoring and concurrent evaluation of NRHM. There are also programmes to institutionalize community monitoring.

Obligations of the district officer:

The principles of RTI can well be applied to the health care services and the various provisions of the NRHM as one method to monitor and exert influence. For example, any private citizen or organization, could examine the construction of a new health centre, see the documents for the medicines that should have reached a particular centre, look at the attendance registers of members of staff,

examine the process of appointments of doctors, nurses, ANMs, look at the process and terms of public private partnership agreements.

Appointment of district RTI officer for health dept: To meet the requirements of the RTI act, each district and each department head would need to designate an RTI officer. In the district unless there is a specific officer designated, the chief medical and health officer would bear this responsibility. The responsibility of this officer would be to respond to any queries that are forwarded to it- and to do so within the time limit. Failure to do so would be actionable.

Documentation of work: Where activities are properly documented and stored, response to RTI queries are easy. Where they are not, it is difficult to comply with the various information sought and it becomes a big drain on administrative time.

Websites: It also helps to place certain categories of information on websites, so that the need to seek information is limited. Thus during the recruitment process, the names of those shortlisted for interviews and those selected could be on the website – if needed with scores and the names of panelists. Or on procurement process- the number of tenders received and the winning tender and its quote could be on the website. Similarly the staff posted in different facilities in the district could be put up on the websites. Not everyone connects to the website, but those with a grievance could certainly do so.

Notice-boards: Some information is best displayed on notice boards. For example the payment entitlement of the beneficiary and ASHA could be put up very visibly on notice boards. Those who actually availed of these payments and those who are on the waiting list to receive the payments could similarly be displayed.

Greivance Redressal: Every department should have a grievance redressal mechanism- where any public citizen or employee could send his grievance in a letter form. The grievance received is given a number, an officer enquires into it, and for all non frivolous grievances gives a reply – verbally or in writing. Only in few cases would further action like inquiry or some administrative measure be required. Having no grievance redressal mechanism and having unreal expectations of such a mechanism are both problems.

All the above steps taken together should lead to a great reduction in the use of requests for information under RTI act. If despite this there are requests received, the register should show the time taken to respond. This more than anything else requires established chain of command and good documentation.

One important consideration in the health sector- is confidentiality. Information about the department is one thing- but about the patients care is another. The patients themselves have a right to see all their own records and know adequately about treatment planned, ongoing and already given. But no one else can demand these as a matter of right, however closely related. In some cases however the spouse or an affected party could be provided with "privileged communication". Thus a married man or woman with



HIV or hepatitis B should inform their spouse. Could spouses demand the report of their partners? To what extent- these are areas that need to be determined on a case to case basis. However barring these exceptional areas, medical records are not open for communication.

There are other areas where interests of other parties are affected, or their permission is needed which would qualify the right to information.

The RTI tool has been used in a very limited way. This is likely to change. It is also important to note that this exercise is most useful as a part of a 'social audit' and not just in isolation. This process of social audit using RTI as a tool and taking the information to 'jan sunwais' or public hearings has been well used by the Mazdoor Kisan Shakti Sangathan, Rajasthan and they have been instrumental in the spread of this strategy to all parts of the country.

What is Social Audit?

Social audit is a process by which an organization's social and ethical performance is looked at, analyzed and reported to the public. In other words, it is a way of making government institutions transparent and accountable to 'the people' using a process that has no legal validity, but a social one. Such is its power, that social audit that can bring about change even without legal action, merely by a public demonstration of wrong doing. Thus, when a public institution is forced to report to the general public, and correct itself, it is really a demonstration of democracy in practice. The RTI Act greatly empowers this process which hinges upon being able to first get the information for a social audit.

Objectives of social audit

- 1. Creating awareness among beneficiaries and providers of local social and productive services.
- 2. Scrutiny of various policy decisions, keeping in view interests and priorities, particularly of the poor and marginalized.
- 3. Bringing corruption and malpractice out in the open.
- 4. Increasing efficacy and effectiveness of local development programmes.

Advantages of social audit

- (a) Enables local democracy.
- (b) Enables community participation.
- (c) Empowers disadvantaged groups.
- (d) Enables collective decision making and sharing responsibilities.
- (e) Trains the community on participatory local planning.

What are 'jan sunwais' or public hearings?

The findings of a social audit may be disseminated or publicized in a number of ways - they may be put

into leaflets and distributed, they may be given to the press and the media or they may be discussed in a public meeting. One home grown type of public meeting, as first developed by MKSS, is the public 'hearing' or jan šunwai. In this, the findings of the social audit are read out to the gathered public and corroborated by them in the presence of the people (officers, doctors etc) of the concerned organization or institution. Journalists and 'eminent' citizens are also often present as witness. If need be technical experts may also be invited. Thus, it is like a public court where the public is a judge. As mentioned above, even without legal validity, the process is often enough to bring about a 'shaming' and a public commitment to change and make reparations. This is then followed up to make sure that the change does not remain restricted to the practice of individuals who may get transferred etc, but becomes institutionalized through better systems for regular monitoring by the public. It also serves to inform people about their rights and the degree to which they have remained unfulfilled through the existing system.

Hamara Paisa Hamara Hisaab

MKSS along with the local residents of Jawaja village (Distt-Ajmer) filed an application in the government hospital in January 2004 under Rajasthan, Right to Information Act. Information sought from the hospital were- how many delivery cases the hospital has received in the last one year and how much money was taken from each delivery cases. This information was purposely asked because as per the government rules all the delivery cases coming to the hospital should be done for free. The other information asked was- from the list of 89 medicines that should be given for free to the BPL card holders, how many medicines have been distributed and to whom.

A jan sunwai (public hearing) on the information obtained was organized in Jawaja. Government officials from medical and non-medical background were present along with few eminent people from the social sector. Villagers testified in front of the whole village and the officers that the doctors take money from them when handling delivery cases. They also said that very few medicines are given to them. They give the excuse that the medicine got over or is under supply. Given this situation villagers are compelled to buy medicines from the chemist shop. On hearing this, government officials strictly mentioned to follow the said rules of the hospitals should be followed to the core.

After the public hearing the government said that all the government hospitals should be open for all 24 hours and the fees asked by the doctors from the villagers before 10 am and after 5 pm should be stopped. Government doctors should not take any fees from the patients (BPL) at any time of the day.

Sushila Devi of MKSS speaks about the importance of Accountability in Democracy and draws a parallel to everyday living. She says when she sends her little son to the market with Rs10 to buy vegetables, she will ask him to account for the amount. If we keep track of these accounts each day, then we definitely and decisively need to demand for accounts of our government because it is "Our money and thus Our accounts"



Review Questions:

- 1. What is the significance of right to information?
- 2. What are the obligations of public authorities towards disclosure of information under the RTI Act? What are the actions the district health officer should take to ensure that his obligations under this Act are met?
- 3. What is the process, fee and time frame for obtaining information under the RTI Act?
- 4. What kind of grievance redressal mechanism is created under the RTI Act?
- 5. How are jan sunwais, social audits being used to support the right to information to enhance overall accountability?

Application Question:

- 1. Create a hand book of information as per the template provided through the link given above providing all the information for your health facility/health programme as required under the RTI Act.
- 2. Discuss the most effective manner of disseminating information related to your office/ department/ organisation.

Project Work:

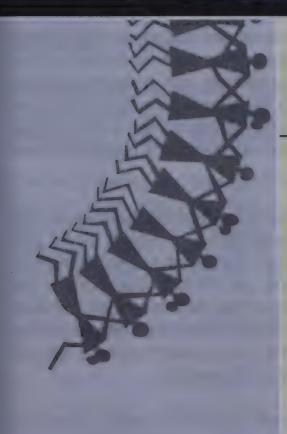
1. Find out if and how many RTI applications have been filed in your office/ department/ organisation and how have they been disposed off. What are the views of important stakeholders on why these questions were asked and what impact the use of RTI had in these specific cases.

NOTES





Food Safety in the District



In this lesson we shall discuss:

The legal provisions made to ensure food safety

The role of Food Safety Officer under the Food Safety and Standards Act, 2006

How at a district level, the government or civil society can act on suspected food adulteration

The provisions of the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act, 1992 (and amendment act, 2003), And how these relate to safeguarding breast feeding as a desirable health practices

What can be done at a district level by government or civil society to prevent or take action on violation of these acts

Introduction

Safe food contributes to health and productivity and provides an effective platform for development and poverty alleviation. Trends in global food production, processing, distribution and preparation present new challenges to food safety. Food grown in one country can now be transported and consumed halfway across the world. People demand a wider variety of foods than in the past; they want foods that are not in season and often eat away from home. Institutionalizing children in schools and childcare facilities means that food for many is prepared by a few and can therefore be the source of major food borne disease outbreaks. A growing number of elderly persons in hospitals and nursing homes and a greater degree of hospitalization also makes for a vulnerable population for whom unsafe food is a serious threat and such contexts gives increased scope for food contamination.

People are becoming increasingly concerned about the health risks posed by microbial pathogens and potentially hazardous chemicals in food. The poor are the most susceptible to ill-health. Food and waterborne diarrhoeal diseases, for example, are leading causes of illness and death in less developed countries, killing an estimated 2.2 million people annually, most of whom are children. Diarrhoea is the most common symptom of food-borne illness, but other serious consequences include kidney and liver failure, brain and neural disorders, and death. WHO and its Member States have responded to these new challenges by recognizing that protecting food safety is an essential public health function. There is a need to for district health officers to understand their legal obligations in this regard.

Another area that requires earnest attention of public health professionals and district health officers is the practice and promotion of breast feeding practices. World over infant milk substitutes marketed by multi-national companies are disrupting the age old practice of breast feeding. There have been important international -initiatives to curb these attempts including the promotion of an International Code of Marketing of Breast-milk Substitutes, and very active civil society movements like IBFAN (International Baby Food Action Network), NAFIA and in India, the BPNI (Breast Feeding Promotion Network of India).

International food standards based on health considerations

The Sixteenth World Health Assembly approved the establishment of the Joint Food and Agriculture Organization of the United Nations (FAO)/WHO Food Standards Programme, with the Joint FAO/WHO Codex Alimentarius Commission (Codex) as its principal organ. The main objective of the Commission is to protect the health of consumers and to ensure fair practice in food trade through the elaboration of food standards contained in a food code (Codex Alimentarius). The objective of Codex is to develop standards for food, protecting the health of the consumers and ensuring fair practices in the food trade. Codex has elaborated many international standards on food safety, and often Member States have used these in national legislation. Recent international agreements managed by the World Trade Organization (WTO) have put even further emphasis on the importance of Codex standards.



Another important international initiative is the WHO Global Strategy for Food Safety, which has been developed with the assistance of experts from Member States and regional advisers in food safety. Its aim is to identify global needs in food safety and to provide a global approach to reducing the burden of food-borne illness.

Regulation in India

The food safety regulation in India is carried out predominantly by way of two laws; the Food Safety and Standards Act, 2006 and the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act, 1992.

The Food Safety and Standards Act, 2006 is a major step towards ensuring food safety in India. The Act has two main objectives; one is to consolidate the laws relating to food in India (details available on Box.1), and second; to establish the Food Safety and Standards Authority of India for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption.

List of Acts repealed by the Food safety and Standards Act, 2006

- 1. The Prevention of Food Adulteration Act, 1954 (37 of 1954).
- 2. The Fruit Products Order, 1955.
- 3. The Meat Food Products Order, 1973.
- 4. The Vegetable Oil Products (Control) Order, 1947.
- 5. The Edible Oils Packaging (Regulation) Order, 1998.
- 6. The Solvent Extracted Oil, De oiled Meal, and Edible Flour (Control) Order, 1967.
- 7. The Milk and Milk Products Order, 1992.
- 8. Any other order issued under the Essential Commodities Act, 1955 (10 of 1955) relating to food.

By way of the powers given by the Act, the Central government can establish a body known as Food safety and Standards Authority of India, the headquarters of which will be in Delhi. The Food safety and Standards authority (referred to as the food authority in the rest of the text) will be the body entrusted with the regulation and monitoring of the manufacture, processing, distribution, sale and import of food. The food authority has the power to come up with guidelines and standards related to food safety.

The food authority has the power to establish a committee called Central Advisory Committee, which advices the food authority in prioritizing its work, identifying potential risks and pooling of knowledge related to food safety and standards. The food authority also has the power to establish scientific panels and scientific committees from whom the food authority can seek scientific opinions. The authorities

responsible for enforcement of the Act will be the Food Authority and the State Food Safety Authorities. The regulations created under the Act will specify the food safety officers who will be enforcing the Act. The State Food Authority will be headed by a commissioner of food safety. The commissioner of food safety will appoint a designated officer not below the rank of a sub-divisional officer to be in-charge of food safety administration at the district level, and food safety officers for local areas.

If the food authority and the commissioner of food safety have reason to suspect that a food may present risk for human health, then in the interests of public's health, they can take appropriate steps to inform the general public of the nature of the risk involved, and the measures to be taken to prevent, reduce or eliminate the risk.

Functions and powers of food safety officers

Presently, the rules under the Food Safety and standards Act, 2006 are yet to be framed. Also states have to formally pass a resolution in their legislatures adopting this act. Until then, The Prevention of Food Adulteration Act, 1954 will remain operational. So it is essential that we familiarize the districts with the procedures being followed by the existing prevention of food adulteration act, 1954, which are largely similar to the 2006 Act. Under the 1954 Act there are already a number of food safety inspectors in place and the procedures for them to act have been laid down.

The Prevention of Food Adulteration Act, 1954, like the 2006 Act covers a wide range of targets. The purpose of the law is to prevent the occurrence of health hazards arising from human consumption of food. The law covers not only foods and drinks, but also additives including natural flavouring agents, and equipment and containers / packages that are used for handling, manufacturing, processing or delivering food.

Under the 1954 Act, the Director of Medical and Health Services or the Chief Officer in charge of Health administration in a State is designated "Food (Health) Authority", The State Government has got the power to define the powers and duties of the Food (Health) Authority. The charge of food safety in the local area is designated "Local (Health) Authority" by the State Government, by notification in the Official Gazette.

In Tamil Nadu, for example, the LHA at district level is the deputy director (Health Services); at PHC level it is the block medical officer; and in municipal areas, the municipal commissioner or the municipal health officer. Smaller municipalities will have a sanitary officer who will be discharging the duties of LHA. In most states the district officer in charge of public health, usually are required to under go a mandatory three month training that imparts them with the skills and knowledge needed for the job. Those municipal health officers who are designated as food inspectors need not undergo the course. Whereas earlier any school completion was adequate for eligibility, now, it is mandatory to possess at least a graduation with chemistry at least as an ancillary subject.



The 1954 Act had a Central Committee for Food standards, as a body created to advise the Central Government and the State Governments on matters arising out of the administration of this Act and to carry out the other functions assigned to it under this Act. This is now to be replaced by the Food Safety Authority.

At the district level. for prevention and action on food adulteration, the 1954 Act and now the 2006 Act envisages the following actions:

- 1. There must be the notification of a Local (Health) Authority(LHA) /district Food Safety Officer and there must be a number of officers designated as food inspectors/local food safety officers.
- 2. The roles of the of Local Health Authority/ Food inspectors (food safety officer under the new act) are as follows:
- Periodically conduct inspection of places where food or food products are manufactured, stored, exhibited or sold and test it for adulteration. A minimum number of such tests per month per inspector is mandatory. The inspector must also respond to complaints or suspicions of food adulteration by conducting inspection which includes collecting samples for testing by the public analyst in the public health laboratory.
- Take samples of food or substances intended to be sold for human consumption (It is important
 to emphasise that while taking samples the cost of the food article has to be paid and a receipt
 has to be taken. Even if the shop-keeper offers the sample for free, the inspector should refuse
 free samples and insist on making payment and getting a receipt).
- When a food safety officer takes a sample of food for analysis, he will have to give notice in writing of his intention to food business operator.
- Seize food that appears to him/her to be made in contravention of the Act.
- Destroy food of perishable nature, if unfit for human consumption, after giving notice in writing to the food business operator.
- Seize books/account documents containing details of adulterant food possessed by him (to be returned within 30 days after taking certified copies).

If any person without reasonable excuse, resists, obstructs or attempts to obstruct, impersonate or threaten, intimidate or assault a food safety officer in exercising his functions he will not only be liable for imprisonment but also pay a fine to the tune of one lakh rupees.

As per the 1954 rules when a food inspector takes a sample, he takes it in three parts- or in a sense three samples. The three samples are for the following reasons:

- One sample is to be sent to the notified public laboratory meant for this purpose. He shall also then intimate the Local (Health) Authority,
- The other two samples (of the three samples collected) is to be sent to the Local Health Authority. The Authority is to keep these two samples.
- In case of the sample sent to the public analyst being lost or damaged, the Local (Health) Authority shall, on a requisition made to it by the public analyst or the food inspector, dispatch one of the parts of the sample sent to it.
- In case the LHA considers the report of the public analyst to be erroneous and wants it re-tested by another public analyst, he could use one of the two samples for the test.
- In case the public health laboratory reports food adulteration and prosecution is initiated, the
 persons who are charged may seek a re-test by the Central Food Authority, in which case also
 one of the two sample kept with the Local Health Authority has to be provided.
- Once the public analyst receives the sample, the public analyst is responsible for testing it and making a report of his findings and sending one copy of his report to the LHA.
- On receipt of the report of the result of the analysis to the effect that the article of food is adulterated, the Local (Health) Authority shall institute the process for prosecution of the person from whom the sample of the article of food was taken and others responsible (as defined under section 14A).
- In addition to this, the LHA should give them a copy of the public health analysts report and
 inform those charged that if so desired, either or both of them may make an application to the
 court within a period of ten days from the date of receipt of the copy of the report to get the sample
 of the article of food kept by the Local (Health) Authority analysed by the Central Food Laboratory.
- The Central Government or the State Government may, by notification in the Official Gazette, require medical practitioners carrying on their profession in any local area specified in the notification to report all occurrences of food poisoning coming within their cognizance to such officer as may be specified in the notification.
- Another important provision of the Act, is that non government organizations and public interest groups and consumer groups can also perform a testing of food samples for adulteration. To do so they should follow the same rules for collecting samples, as prescribed for the food inspectors. In addition non government organizations can use simple kits disseminated by the department to make tests for food adulteration. Though this is not enough evidence to initiate prosecution, it does indicate where to take samples from as part of a formal investigation and it also can be used to inform and protect communities from food adulteration.

The Prevention of Food Adulteration Rules, 1955, which followed from the 1954 Act, specify among others, the permitted colours, anti-oxidants, emulsifying and stabilizing agents, flavouring agents,



addictives, sequestering and buffering agents etc. to be used in the food. The rules specify that the relevant details needs to be printed on the packed food. These rules are available on the website and are in force till the new rules would be announced.

Issues of implementation:

There are many problems with implementation of this Act and we need to understand some of these:

- The act does not automatically come into force everywhere. The areas (municipal) where the act is applicable needs to be notified in the official gazette. In un-notified areas the act cannot be implemented. For notification the panchayat or local body must pass a resolution stating that it wants to implement the act. This is essential because there are some minor charges, for sending the sample etc, which has borne by the local body. Since most local bodies are not aware of this, considerable effort is needed from the local food safety officers, to explain it to them, get such a resolution passed, then inform, the government and get a gazette notification issued. As a result, in even a relatively well administered state like Tamil Nadu there are several areas where the Act cannot be implemented.
- Availability of facility for proper laboratory analysis. Not all laboratories are able to manage
 the volume of tests they are required to do, nor the range of tests that is required of the,
 Especially tests like pesticide residue analysis, require sophisticated equipment and good
 training and many public health laboratories are now equipped with this.
- Availability of properly trained food inspectors (3 months mandatory training stipulated) in sufficient numbers. The problem is both with sanctioning the required number of posts and with filling up the sanctioned posts and training the incumbents.
- Lack of awareness amongst both consumers and authorities about the provisions of the Act and the action required of them. There is very little knowledge of this Act, even amongst those charged with implementing it. When a medical officer in a district becomes a food authority there is no induction programme, there is no guidebooks or instruction manuals available and there is sometimes not even a senior staff administered section where some institutional memory of this act and its implementation can be maintained. If this is the situation in the authorities, amongst consumers, the level of awareness of rights and of the action they need to take is very limited. Also the process of complaint and litigation is not easy and is very cumbersome- putting off most potential complainants.

The Prevention of Food Adulteration Act as well as rules will be repealed by the Food Safety and Standards Act, 2006, but in essence, except on a few points, they are the same. Action on this should therefore start irrespective of whether the state has passed the necessary state legislation for this act or not and notified the new rules and regulations. Advocacy to notify the rules and start implementing the 2006 Act is also important.

RESERVED FOR FREE PARTY.

The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act, 1992 and 2003

Breast milk used to be considered the natural entitlement of babies in developing countries. However, it is increasingly becoming recognized, and evidence from NFHS 3 confirms this, that we are facing a dismal situation in exclusive breast feeding.

One of the major causes for this, and the obstacles to achieving universal exclusive breastfeeding is the aggressive promotion of illegal infant milk substitutes and other infant formulae, especially in the 1980s and 1990s that dampened the promotion of breastfeeding and appropriate feeding practices in India. Every form of media was used to spread the message that formula milk was better than breast milk. Many inducements, (discussed in the lesson on rational drug therapy), were given to parents and doctors to promote expensive and unnecessary formula milk and milk bottles. Though this situation may still persist in practice, a fierce and determined process of public action has led to the regulatory Infant Milk Substitutes Act (IMS Act), passed in 1992. The Act was also inspired by *International Code of Marketing of Breast-milk Substitutes (WHO, 1981)*.

The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992, (IMS Act,1992) was enacted to regulate production, supply and distribution of infant milk substitutes, feeding bottles or infant foods. It was felt that the IMS Act, if properly promoted at states and districts, could help to stop promotion of infant milk substitutes. However, during the course of its implementation, the Government of India and other notified agencies had found that baby food manufacturing industries used to take undue advantage of the loopholes of the IMS Act and continued to influence the women and mothers to their babies with substitute milks. Government of India enacted the new Act know as IMS Act 2003 after making necessary changes in the IMS Act 1992 with the prime objective to obliterate the ambiguities within the law. The IMS Act 2003 restricts activities connected with promotion, labeling of infant foods, distribution of education materials and funding health workers and their associations.

Salient Features of IMS Act 1992:

- Prohibit any kind of promotion of infant milk substitutes, feeding bottles and infant foods to protect breastfeeding from commercial influences.
- Educate pregnant women and lactating mothers about breastfeeding to create awareness about the benefits of breastfeeding. The aim of the IMS Act here is to provide accurate and factual information about breastfeeding to reverse its decline and prevent incorrect information from reaching to mothers.
- Restrict and control the use of infant milk substitutes and infant foods, which can otherwise be harmful.
- Define the roles and responsibilities of healthcare institutions and health workers to ensure optimum breastfeeding practices.



- The implementing authorities are the same as under prevention of food adulteration act. The food inspector appointed under section 9 of the PFA act, 1954 is the authorised officer under the IMS act (or any officer not below the rank of class I officer authorised by the state government). This means that the district health officer and the local health authorities many of whom are medical officers- and the food safety officers are all implementing authorities of this Act.
- Also note that specific NGOs can be given the powers to act as implementing agencies, by notifying their name for this purpose in the official gazette.

What is banned under the IMS Act?

- 1. Commercial promotion of baby food for consumption of children under the age of two years.
- "Promotion means using any direct or indirect method of encouraging a person to purchase or use these products". Often companies promote their products directly to the families or through doctors or health workers in the healthcare system e.g., a doctor prescribing these products without assessing the need of introduction.
- 2. All advertisements on infant milk substitutes in any media (print media e.g. newspapers, pamphlets etc., electronic media e.g. television). The 2003 act is very particular that any attempt to make an impression that infant milk substitutes are in any way equal or better than breast milk will attract penal provisions of the IMS act.
- 3. Distribution of samples and gifts or sending mailers to pregnant women, lactating mothers, doctors, nurses etc.
- 4. Donation and distribution of baby foods, educational material, and equipment to the healthcare system or to mothers directly. (The baby care book released by Nestle India Ltd with the intention of educating mothers of infants, as an educational material has run into controversies for their alleged violation of section 7 and 9 of the IMS Act). The 2003 act prevents donation or distribution of infant milk substitutes or feeding bottles or infant foods to any person except to an orphanage.
- 5. Pictures of an infant or a woman or both or a graphic on the label of infant food products.
- Companies often use pictures of teddy bear, a bird, cartoons etc. on the labels and information packs to idealize their products. Pictures of healthy babies or such graphics catch the attention of the mothers and families. This also overshadows the factual information contained on the labels for the benefit of the mother and the family.
- 6. Use of the Healthcare System for Display such as posters, hoardings etc. and distribution of promotion materials in hospitals or chemist shops. The Act prohibits offering gifts or making any payment to health workers or to any member of his/her family. Funding professional seminars, meetings, conferences,

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educational courses, contests, fellowships, research work or sponsorships are also been prohibited. This is following the observation that companies have been indulged in the practice of influencing the doctors and using them subsequently for advising mothers in using their baby food products. (Glaxo Smithkine Consumer Healthcare has come up with posters which is to be put on clinicians visiting rooms has also been alleged to violate section 7 of the IMS act, for depicting the pictures of pregnant mother).

7. Giving commission to company staff on the basis of sales of its products. This practice, if allowed, can lead to unethical practices, by both the doctors and the company staff.

How can the IMS Act apply at the district level?

As part of our district level action on accelerating child survival and reversing malnutrition, we must undertake the following steps to protect breast feeding under the IMS Act:

- Ensure that the Act is well known and understood by the district health authorities who are also authorities under the prevention of food adulteration act and the food safety act.
- Also increase awareness of the act amongst health professionals, PRIs and NGOs so that they can themselves monitor the companies' illegal promotion of baby foods.
- Distribution of publicity materials about IMS Act in the local languages of the district so as to increase awareness of families and communities. Also towards the same end, organize public meetings/ seminars, discussion on IMS Act at radio and television progammmes and publicizing it through local newspapers.
- Involve the local ICDS workers, Legal Service Authorities, and consumer groups and NGOs in spreading the provisions of IMS Act and benefits of breastfeeding, and to watch the activities of the baby food companies and its distributors and report on make violation of the provisions of this act as well as more generally about their marketing trends.
- Develop a reporting system for the violation of IMS Act in the district. Setting up a monitoring team comprises of legal, heath, medical and district administration.
- Any of the authorities can take action once he or she receives a complaint. They should file the
 necessary papers with the evidence to the assistant public prosecutor and then file a case against
 the offender. The District Magistrate, the Sub Divisional Magistrate or the Commissioner of Police
 should be kept informed.
- They may also write a written complaint to the organizations authorized by GOI to monitor the violations of IMS Act.



Review Questions:

- 1. What are the responsibilities of the Food Safety officer under the Food Safety and Standards Act, 2006.
- 2. Why does a food safety officer take three samples of a suspect food?
- 3. What are the problems being faced with implementation of the Food Safety and Standards Act, 2006.
- 4. What are the salient features of the IMS Acthow does it prevent the promotion of infant mlk substitutes.
- 5. What roles can NGOs play in implementing the food safety act and the IMS act. How can government empower NGOs to play this role?

Application Question:

 Get hold of a packaged food and see the details available on its cover (e.g. Maggie noodles). What are the details that should be there in such a label. How does one check whether these are sanctioned chemicals and ingredients?.

Project Work:

- 1. Meet a few food inspectors/food safety officers in the district. Find out how many complaints they have received and the action taken as well as a number of cases of adulteration they have tried to take action on. Make sure you select officers who have been associated with filing cases.
- 2. Try and identify a number of families which are using infant milk substitutes instead of breastmilk. Find out why they happened to do this. Where did they learn about the milk substitute they are using? Try to identify the ways in which IMS had been promoted to these families.

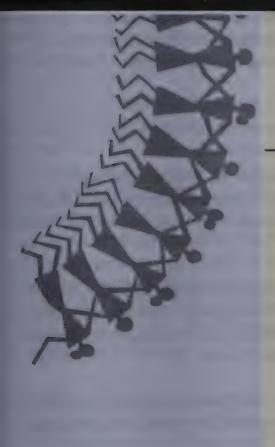
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Lesson SIX

The Control of Drugs at the district level



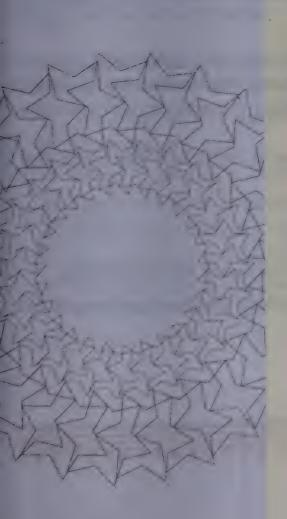
In this lesson we shall discuss:

Why must drugs be regulated

The laws regarding drugs' regulation, manufacturing, advertising, marketing, distribution, price control, patenting, in India

Areas/Issues related to regulation of drugs

Evolving laws/ policies on drugs, patent/ TRIPs



Introduction

Medicines are important both to a country's economy and to the health of its people, but these two interests can conflict. Worldwide, it is estimated that over half of all pharmaceuticals /drugs are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take their medicine correctly. The inappropriate use of medicines is not only widespread, it is costly and extremely harmful both to the individual and the population as a whole. (see chapter in book 11)

Why must medicines be regulated?

The use of ineffective, poor quality, harmful medicines can result in therapeutic failure, exacerbation of disease, resistance to medicines and sometimes death. It also undermines confidence in health systems, health professionals, pharmaceutical manufacturers and distributors. Money spent on ineffective, poor quality medicines is wasted – whether by consumers or governments.

There is an 'information asymmetry' between those who manufacture/sell medicines and patients/ consumers, who are not equipped to make independent assessments of the quality, safety or efficacy of their medicines; Desperate patients may buy ineffective or even toxic medicines; and misuse of medicines, such as antibiotics, can have serious implications for individual and public health.

Once medicines are prescribed to patients, others, such as dispensers and drug sellers, become involved. Regulation is also needed to ensure that these interactions do not adversely affect treatment outcomes³.

The production and distribution of medicines require public oversight and stewardship. Unlike ordinary goods and services, an unregulated medicines market place will fail: it would be not only inequitable, but also inefficient, and probably dangerous to public health.

The task of overseeing and regulating the medicines market place is often formidable. Thousands of products may be available, supplied by large numbers of manufacturers and handled by numerous importers, wholesalers and retailers. Three main components of regulation in the medicines market are identified in a recent multi-country study by WHO. They are

- 1. Product registration: assessing and authorizing products for market entry, and monitoring their effectiveness and safety after entry
- 2. Regulation of manufacturing, importation and distribution
- 3. Regulation of medicine promotion and information

In some countries a fourth component, price control, is a recognized objective of medicines policy.

If national laws and regulations relating to medicine are inconsistent or incomplete they can frustrate the objectives of overall health policy.



Drug regulation in India- historical overview:

Most countries have a medicines regulatory authority and formal requirements for registering medicines. However, medicines regulatory authorities differ substantially in their human and financial resources, and in their overall effectiveness. Fewer than one in six WHO Member States have well-developed drug regulation and two in six have no or very little drug regulatory capacity.

India already had the Poisons Act (1919), the Dangerous Drugs Act (1930) and Opium Act (1878) to start with. But to respond to the needs of rapidly expanding pharmaceutical production in the early twentieth century, the government introduced a a comprehensive legislation/ln 1931, a Drugs Enquiry Committee under the Chairmanship Lt. Col. R. N. Chopra was set up and it submitted a report which forms the basis of our drugs control. The report suggested creation of drug control machinery at the centre with branches in all provinces. For an efficient and speedy working of the controlling department the committee also recommended the establishment of a well-equipped Central Drugs Laboratory with competent staff and experts in various branches for data standardization work. Under the guidance of the Central Laboratory, it was suggested, small laboratories would work, in the provinces. For the training of young men and women, the Committee recommended the permission of Central Pharmacy Council, and the Provincial Pharmacy Councils, with registrars who would maintain the lists containing names and addresses of the licensed pharmacists.

The Drugs Act was passed in 1940 partly implementing the Chopra recommendations and with the achievement of independence in 1947 the rest of the required laws were put on the Statute Book. In 1985, the Narcotic Drugs and Psychotropic Substances Act was enacted repealing the Dangerous Drugs Act 1930 and the Opium Act of 1878.

Drug Control acts in Place:

At present the following Acts and Rules made thereunder that govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India are:

- 1. The Drugs and Cosmetics Act, 1940 (with Drugs and Cosmetics Rules, 1945);
- 2. Pharmacy Act, 1948;
- 3. Drugs (Control) Act, 1950;
- 4. Drugs and Magic remedies (Objectionable Advertisements) Act, 1954;
- 5. Drugs (Price Control) Order, 1955;
- 6. Narcotic drugs and Psychotropic Substances Act, 1985;
- 7. The Infant Milk Substitutes, Feeding Bottles And Infant Foods (Regulation of Production, Supply & Distribution) Act, 1992 (and Rules 1993);

Drug control at the Centre

The Drugs and Cosmetics Act, 1940 (with Drugs and Cosmetics Rules, 1945)

Under the Drugs and Cosmetics Act, 1940, the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the state authorities while the Central authorities are responsible for approval of new drugs, clinical trials in the country, laying down standards for drugs, control over the quality of imported drugs, coordination of the activities of state drug control organisations and providing expert advice with a view of bringing about uniformity in the enforcement of the Drugs and Cosmetics Act. Drug Controller General of India is responsible for approval of licences of specified categories of Drugs such as blood and blood products, I.V fluids, Vaccine and Sera. The Central Drugs Standard Control Organization (CDSCO) is located at Nirman Bhawan, New Delhi, and functions under the Directorate General of Health Services.

The Drugs and Cosmetics Act, 1940 (with Drugs and Cosmetics Rules, 1945) covers Allopathic, Ayurvedic, Homeopathic, Unani and Siddha drugs. The Act has made it punishable to import, manufacture, distribute and sale of misbranded, adulterated and spurious drugs.

The Drugs and Cosmetics Rules specifically deal with standards for identity, purity and strength of Drugs. The standards encompass drugs included in the Indian Pharmacopoeia, the British Pharmaceutical Codex or the National Formulary of the United States; veterinary drugs; patented or proprietary medicines; surgical dressings; sterilised umbilical tapes; standards for substances (other than food) intended to affect the structure or any function of human body; contraceptives (including condoms); medical devices; standards for substances intended to be used for the destruction of vermin or insects which cause disease in human beings or animals; disinfectants; ophthalmic preparations; and list of colours permitted to be used in drugs. There is a separate section dealing with standards of Ayurvedic, Siddha and Unani Drugs. The rules also talk about standards for conduct of clinical trials. It has also listed down the procedure and elements for the formation of Ethics Committee for sanctioning and monitoring of clinical trials.

The Drugs And Magic Remedies (Objectionable Advertisements) Act, 1955 & Rules 1955.

The Drugs And Magic Remedies (Objectionable Advertisements) Act, 1955 was enacted to prohibit the advertisement of drugs for remedies alleged to possess magic qualities and to provide for matters connected therewith.

The Act defines "magic remedy" as including a talisman, mantra, kavacha, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals.

Again the district officer is the main officer responsible for monitoring compliance with this act and could

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be the complainant and would ensure that the matter is reported to the drug controller and to the district legal authorities for actions against persistent offenders. Again this is a law which is poorly observed.

The Narcotic Drugs and Psychotropic Substances Act, 1985

The Narcotic Drugs and Psychotropic Substances Act, 1985 was enacted to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances and for matters connected therewith. It is necessary for chief medical officers to ensure compliance with this act.

Drugs (Price Control) Order, 1955

The Essential Commodities Act, 1955 was an enacted to provide, in the interests of general public, for the control of the production, supply and distribution of, and trade and commerce in, certain commodities. By way of the powers conferred by section 3 of the Essential Commodities Act, 1955, the Central Government has come up with the Drugs (Price Control) Order, 1955 in order to ensure equitable distribution and availability at fair prices of drugs in India. The Government, after making such inquiry as it deems fit, fix from time to time, by notification in the official Gazette, a maximum sale price at which such bulk drug shall be sold. And no person shall be allowed to sell a bulk drug at a price exceeding the maximum sale price (plus local taxes) fixed by the Government. Drugs were categorized into three groups. Those on which strict price controls were in place with a limited mark up allowed for profits, those on which price controls were placed but a more liberal mark up was allowed and finally a third category where there was mark up.

Today, the number of drugs covered by price control are very limited and its implementation is very weak. But even when this mechanism was at its peak there was considerable avoidance of controls by simple guises – for example selling the drug as a branded combination drug with other constituents- and implementation was very weak. The chief health and medical officer of the district is the legal authority for monitoring its adherence – but few would be aware of the act.

Registration of Drugs

Most countries of the world, including developing ones, have a well-organised system of registration of drugs permitted to be imported or manufactured. Thus, master files of products are submitted for evaluation by the regulatory agencies. It is only after the furnished data has been found adequate that the product is registered in the country. No such centralised system exists in India. There is need for checking this deficiency by introduction of the registration procedures which will also help in elimination of irrational/sub-therapeutic products. Adequate machinery has to be created in the CDSCO for the purpose.

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Pharmacovigliance

Modern medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence continues to mount that adverse reactions to medicines are a common, yet often preventable, cause of illness, disability and even death. In some countries, adverse drug reactions (ADRs) rank among the top 10 leading causes of mortality. Aside from the intrinsic dangers associated with the products themselves, individual patients may exhibit particular and unpredictable sensitivities to certain medicines. In addition, if more than one medicine is prescribed, there is always a risk of negative interactions. Adverse drug reactions (ADRs) may not be detected until a drug is used after launch, in part because animal toxicology studies are often poor predictors of human effects, the sample size of the clinical trials are usually small, the duration of the clinical trials are often short, and susceptible patients (e.g., those with concurrent disease or medications) are often not included in trials. The selection and use of the best and safest medicine(s) for a given individual out of the many choices available thus requires considerable skill on behalf of the prescribing practitioner.

India has designated centers for reporting adverse drug reactions, but there are neither widely advertised or known and some of them are poorly functional. Reporting is also not mandatory. For the district public health system, there is a need for the district health officer to play the role of being the center that collates reports from within the district and transmits it to the ADR centers and follows up on this.

WHO Certification Scheme

The WHO Certification Scheme on the quality of Pharmaceutical products moving in International commerce (1975) is a nonbinding set of guidelines which can be accessed by both developed and developing countries. India is currently following the certification scheme. The WHO Scheme has no legal status and it can be superseded by national legislation.no need for separate head for this – take this into the section on drug control by center, In most procurement institutions prequalification of the manufacturing enterprise requires that it is duly certified and that this certificate is valid in duration. Standards have been laid down by WHO – called Good Manufacturing Practices and enterprises are certified against these - which are largely the set of standards followed by India. Many states however exempt their procurement processes from insisting on such certification – which makes it more difficult to guarantee quality.

If a district officer is doing independent procurement- then it is important for the district officer to ensure compliance with this. It is impossible for the district procurement officer to ensure that an industry has quality standards built in, but it can ensure that the industry if certified by an appropriate authority for this purpose.

A district officer also has to send test samples from every batch of supplies that was delivered to it by two independent laboratories for quality testing. Identifying these agencies is a process. For these reasons it is preferable if the procurement process is managed at the state level, but responsive to the district



needs. If a sample of drugs tested fails the quality test, payment must be withheld. But in parallel further samples must be sent to government laboratories earmarked for this purpose. Failure of the tests here, would now make it possible to initiate criminal action against the company for providing spurious or adulterated drugs.

Review Questions:

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- 1. What are the laws that regulate drugs and pharmaceuticals in India?
- 2. What are the roles that district health officers can play in improving the implementation of these rules.

Application Question:

1. Discuss the role of Indian pharmaceutical industries in providing drugs at reasonable rates in the Indian market.

Project Work:

1. Is there drug procurement done in the district? How is the quality of supplied drugs ensured?



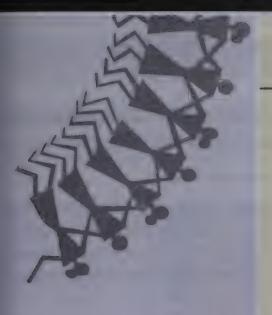
Lesson SEVEN

Legal Position on Declining Sex Ratio and Abortion Rights in India

Law against Pre-birth Sex Selection (PC & PNDT Act)

And

Law for Medical Termination of Pregnancies (MTP Act)



In this lesson we shall discuss:

PC & PNDT Act, 1994:

Basic thrust and purpose of the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection)
Act (popularly known as PNDT or PC & PNDT Act)
Offences/ crimes under the PC & PNDT Act
Legitimate uses of the technologies for pre conception and pre natal diagnosis and sex-selection
Meanings of terms — 'pre natal diagnostic techniques'
(PNDT) and 'sex-selection'
Authorities set up under the PC & PNDT Act for policy making and implementation and their roles
Complaint mechanism under the PC & PNDT Act
Reasons for weak implementation of the PC & PNDT Act and how implementation can be strengthened

MTP Act, 1971:

Who can legally terminate a pregnancy under the MTP Act When can a pregnancy be terminated under the MTP Act Where can a pregnancy be terminated under the MTP Act Duties of the Chief Medical Officers under the MTP Act Essentials of safe and legal abortions
Rights of women under the MTP Act

Inter-sectionality between the two laws:

Overlap and inter-sectionality between the issues of prebirth sex selection and determination on one hand and women's access to abortion, and what are the implications that must be understood

INTRODUCTION:

In this chapter we would basically look at the provisions of:

- Law for arresting the plummeting sex ratio in India (The "Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act" or what is popularly known as "PNDT Act" or "PC & PNDT Act") of 1994; and
- Law to provide access to women to services for medical termination of pregnancy or abortions (The "Medical Termination of Pregnancy Act" or what is popularly known as "MTP Act") of 1971.

It is important to look at these laws as both of them place several duties on the district health officers and they also have huge impact on two of the highly sensitive and vital issues of rights that have a bearing on health and also on the wider gender and social structures.

Towards the end of this chapter we would also look at an emerging contentious interplay of the these two laws at social level— the right to gender balanced social order, that has ironically come to be pitted against the right of women to their reproductive lives. Indeed this is a classic test for the rights based approach which must have the strength not to let down either of the two rights and yet let each of the two remain effective.

There are no easy solutions to such complex issues, but if we understand the complexity, we appreciate better the inherent limitations of laws or legal responses on social issues and the need to combine laws with social responses for best results.

LAW AGAINST SEX SELECTION/ SEX DETERMINATION:

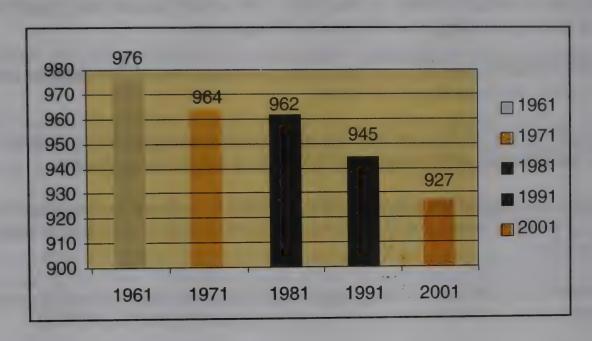
While sex ratio at birth in a healthy population should be around 950, in India there has been a drastic decline in the juvenile sex-ratio (number of girls per 1000 boys for 0-6 years age-group) in the last 50 years. This is the result of the logical progression of the socio-cultural practice of son preference in India, which was historically manifested in female infanticide and general deprivation and disempowerment of women in Indian societies. Since the early 1980s, this practice began to also manifest in gross misuse of medical diagnostic technologies that made it possible to determine the sex of the foetus (pre natal sex determination) and later on, to even select the sex of the foetus (sex selection). From 976 girls per 1000 boys in the year 1961, the number fell to 927 in 2001. In 2001, the child sex ratio was 754 in Fatehgarh Sahib (Punjab), 770 in Kurukshetra (Haryana), 798 in Mahesana (Gujarat). In affluent States like Maharashtra, Gujarat, Punjab, Himachal Pradesh, Haryana, where people have much better access to technologies, there was more than 50-points decline in child sex ratio.

The need to enact a specific law arose due to the growing misuse of diagnostic technologies which are



actually meant to be used for detecting foetal abnormalities. The misuse that this law sought to curb was to carry out pre-natal tests on the pregnant mothers for the purpose of determining the sex of foetus (to be able to eliminate the foetus if it was a female one). The law which is now called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act (PC & PNDT Act) was originally passed in 1994 towards 'regulation' and 'prevention' of misuse of 'pre-natal' diagnostic techniques (PNDT). Eight years later, in the year 2002, the law had to be reviewed thoroughly and it was considerably tightened as despite the earlier law the tests were being carried out more rampantly than before. But this amendment also brought "pre-conception" diagnostic techniques (PCDT) within the fold of the Act as technological advances made it possible to select the sex of the foetus even before conception. The Act at it stands today aims to totally "prohibit' the misuse of both such techniques – pre-natal as well as pre-conception.

Trend of decline in child sex ratio (number of girls per 1000 boys for 0-6 years age group) in last 40 years is:



SALIENT FEATURES1 OF THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) ACT, 1994 ("PC & PNDT ACT")²

WHAT IS THE MAIN DRIVING FORCE BEHIND THE PC & PNDT ACT?

The basic thrust of the PC & PNDT Act is three fold, united by the objective of averting further decline in sex ratio:

Prohibit selection of sex of the foetus, both before and after conception

¹ Portions of this section have been adapted from a poster published by Human Rights Law Network, authored by Shruti Pandey.

² The complete text of the PC & PNDT Act can be accessed at: http://pndt.gov.in/writereaddata/mainlinkFile/File50.pdf and the Rules notified thereunder at: http://pndt.gov.in/writereaddata/mainlinkFile/File51.pdf

Ban the misuse of 'pre-conception diagnostic techniques' (PCDT) and 'pre-natal diagnostic techniques'
(PNDT) for sex selection / determination

Prescribe legitimate uses of Pre Natal Diagnostic Techniques

Key Features of the Act:

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WHAT ARE THE OFFENCES/ CRIMES UNDER THE PC & PNDT ACT?

All the following medical malpractices and acts of omission or commission are declared as amounting to committing offences under the PC & PNDT Act:

- 'First and foremost, 'sex selection' including any technique, procedure, test, administration, prescription or provision of anything, before or after conception, for the purpose of ensuring or increasing the probability of birth of male child. This would include even Ayurvedic pills or any alternative therapy claiming to be effective for this purpose.
- Misuse of PC & PNDT, even by a qualified person, solely for sex-determination and in conditions not falling under the exceptions (see below)
- Conducting PC or PNDT by a person, including those working on honorary basis, without the requisite qualification and experience/ training as prescribed in the Act
- Seeking or encouraging the misuse of PC or PNDT by husband or the woman herself (unless she was compelled to undergo such techniques) on the woman or husband, or even by a relative, for sex selection
- Communication of the sex of the foetus to the woman or her husband or relatives, through words, signs or any other manner, by the person conducting the PC or PNDT
- Issue, publication or circulation of any advertisement of facilities or any means of selecting or determining sex of the foetus before or after conception. The advertisement may be in any form: notice, circular, label, wrapper or any other document, advertisement through internet or any other media in electronic or print form, hoarding, wall-painting, signal, light, sound, smoke or gas.
- Non-registration of the places where PNDT are carried out: Genetic Counseling Centre (advising PNDT of both kinds: procedures or tests), Genetic Clinic (conducting PNDT procedures), Genetic Laboratory (conducting PNDT tests), including the vehicle used as Genetic Clinic. (See Box)
- Use of unregistered places for carrying out PC & PNDT



- Sale of machines or equipment capable of detecting sex of foetus, to unregistered units or practitioners
- Non-maintenance of medical records (as per Forms D, E, F in the Act)
- Non display of registration certificate at some prominent place in the premises conducting PC
 & PNDT
- Non- availability of PC & PNDT Act in the unit carrying out the PC & PNDT

Every offence under the Act is cognizable, non-bailable, and non-compoundable

PUNISHMENTS:

The punishments for major offences involving sex selection or sex determination and non-maintenance of records (violation of section 5 and 6 of Act) are:

- Imprisonment of upto 3 years (5 years in case of subsequent offence) and fine of Rs. 50,000 (Rs. 1 lakh in case of subsequent offence). However, this does not apply to any woman who was compelled to undergo such diagnostic techniques or such selection.
- Name of the registered medical practitioner shall be reported by the Appropriate Authority to the State Medical Council concerned for taking necessary action including suspension of the registration if the charges are framed by the court and till the case is disposed of, and on conviction for removal of his name from the register of the Council for a period of five years for the first offence, and permanently for the subsequent offence.

For registration related offences, the AA may:

- Suspend or cancel the registration, as per the magnitude of the violation.
- During the period of suspension of registration, the equipment will be sealed and signed and kept with the owner.
- After cancellation of the registration, the equipment has to be sealed and seized.
- For non-registration, 5 times the registration fee may be charged as penalty and an undertaking hall have to be furnished as per the PNDT Rules.

For advertisement related offences, the prescribed punishment is:

- Imprisonment which may extend to 3 years; and
- Fine which may extend to Rs, 10,000

For other offences, the prescribed punishment is:

- Imprisonment which may extend to 3 months; and
- Fine which may extend to Rs. 1,000 for first offence.
- Additional fine upto Rs. 500/- per day may be levied for the period of contravention for subsequent offence.

WHAT ARE THE IMPLICATIONS OF CONTINUING DECLINE IN SEX RATIO IN POPULATION, FOR THE FUTURE?

- Sharp decline in ratio of women to men
- Rise in sexual offences against women
- Rise in child sexual abuse
- Increase in trafficking of women for sexual exploitation
- · Rise in domestic and all other forms of violence against women
- Decreased social and economic mobility of women
- · Rise in incidence of 'bride price' and other changes in patterns in societal, marital and familial relationships

It is a myth that fewer women in population would raise the status of women in society! More likely, women's status is likely to deteriorate overall as experiences have shown.

WHAT LEGITIMATE USES OF PNDT DOES THE ACT PERMIT?

The Act allows use of PNDT only to detect chromosomal abnormalities, genetic metabolic disease, haemoglobinopathies, sex-linked genetic diseases, congenital anomalies, or other abnormalities / diseases in the foetus as specified under the Act.

But the use of PNDT to detect these abnormalities is permitted only in registered places/units (including vehicles) and by qualified persons only:

- ▶ When the pregnant woman:
- Is above 35 years of age or
- Has undergone two or more spontaneous abortions or foetal losses or



- Has been exposed to potentially hazardous teratogenic agents such as drugs, radiation, infection or chemicals or
- Has a family history of mental retardation or physical deformities such as spasticity or any other genetic disease

In addition, all the above are subject to mandatory informed consent by the woman.

OR

▶ Under any other condition specified under the Act (like, ultrasound tests can be conducted in 23 conditions added in Form F under the Act, subject to strict record maintenance.)

It is pertinent to mention that every sonologist is required to fill **Form F** before conducting an ultrasound on a pregnant mother. The form has 19 questions including the reason for conducting the sonography, along with patient detail. Every ultrasound clinic is required to submit Form F to the appropriate state authority by the 5th of every month, and keep the record of Form F with them for three years.

WHAT ARE "PRE NATAL DIAGNOSTIC TECHNIQUES" (PNDT) AND "SEX SELECTION"?

"PNDT" includes all pre-natal diagnostic 'procedures' and 'tests':

- "Pre-natal diagnostic procedures" means all gynaecological, obstetrical or medical procedures, both invasive and non-invasive, for sex selection, both before and after conception:
 - invasive pre-natal diagnostic procedures are utilized to remove samples from a woman or a
 man, both before and after conception, of amniotic fluid, chorionic villi, embryo, blood or any other
 tissue or fluid, for conducting any type of analysis or test like: amniocentesis, chorionic villi biopsy,
 foetal skin or organ biopsy, cordocentesis,
 - non-invasive pre-natal diagnostic procedures include ultrasonography, foetoscopy
- "Pre-natal diagnostic tests" means test or analysis conducted on the samples received by the
 conduct of pre-natal diagnostic procedures such as amniotic fluid, chorionic villi, blood, conceptus or
 any tissue removed from a woman or a man, both before and after conception

Sex selection includes:

- Procedure
- Technique
- Test

- Administration
- Prescription
- Provision of anything for the purpose of ensuring or increasing the probability that an embryo will be of a particular sex.

Registration and qualification requirements for places & professionals:

Genetic Counselling Centre means: an institute, hospital, nursing home, or any other place by whatever name called which provides genetic counseling to patients.

Genetic Clinic means: any clinic, institute, hospital, nursing home, or any other place by whatever name called which is used for conducting pre-natal diagnostic procedures.

Genetic Laboratory means: any laboratory and includes a place where facilities are provided for conducting analysis or tests of samples received from Genetic Clinic for pre-natal diagnostic test.

For a genetic counseling center, the gynaecologist or paediatrician practising there must have 6 months experience or 4 weeks training in genetic counseling.

For a **genetic clinic**, the **gynaecologist** should have adequate experience in *prenatal diagnostic procedures* i.e. should have performed **at least 20** procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields.

A registered medical practitioner (who possesses any recognized medical qualification as defined in the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register) practising in a genetic clinic should have Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning.

Medical Geneticist includes a person who possesses degree or diploma in genetic science in the fields of sex selection and pre-natal diagnostic techniques or has experience of not less than two years in any of these fields after obtaining any one of the medical qualifications recognized under the Indian Medical Council Act, 1956; or a post-graduate degree in biological sciences, but merely possessing a certificate does not make one a qualified medical geneticist.



AUTHORITIES UNDER THE PC & PNDT ACT:

(a) Policy making body: A Board is required to be constituted by the Central Government which is known as the Central Supervisory Board. The Act makes provision for inclusion of government officials, specialists as well as representatives of welfare organizations in this Board.

It is mandatory for the Board to meet at least once in six months and its functions as specified under the Act are:

- i) Advise the Central Government on policy matters relating to use of pre-natal diagnostic techniques, sex selection techniques and against their misuse;
- ii) Review and monitor implementation of the Act and the rules made thereunder and to recommend to the Central Government changes in both;
- iii) Create public awareness against the practice of pre-conception sex selection and pre-natal determination of sex of foetus leading to female foeticide;
- iv) Lay down code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics:
- v) Oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure its proper and effective implementation.

The Board is also to perform any other functions as may be specified under the Act such as specifying abnormalities or diseases for which pre-natal diagnostic techniques can be conducted or the conditions which are necessary to exist before the conduct of these techniques. Thus the Act envisages the Board as the main body which is to make recommendations on policy maters and on amendments that are necessary in the Act.

Under the amended provisions of the Act, a State Supervisory Board or the Union Territory Supervisory Board is also required to be constituted by each State and Union Territory having a Legislature with a constitution similar to the Central Board, and similar advisory functions.

(b) Implementing authorities:

The role of implementation of the Act has been assigned to the "Appropriate Authorities" (AA) which must function with the aid and advice of an Advisory Committee.

The Central Government is required to appoint one or more Appropriate Authorities for each of the Union territories;

• Under the amendments, a multi-member body has been provided as the State Appropriate Authority consisting of:

i) an officer of or above the rank of the Joint Director of Health and Family Welfare-Chairperson;

ii) an eminent woman representing women's organization; and

iii) an officer of Law Department of the State or the Union Territory concerned.

Under the directions of the Supreme Court, Appropriate Authorities are to be appointed at district
and sub-district levels as well. At the District level, the Chief Medical Officers or the Civil
Surgeons have been designated as the Appropriate Authorities. Recently the Union
Government has recommended making the District Magistrate the Appropriate Authority and
many states have followed this us. At the sub-district level, the practice varies from State to
State.

Functions of the Appropriate Authority are:

- Receive applications for registration (in duplicate in **Form A** accompanied by an Affidavit with undertaking of not carrying out sex-determination or sex selection and displaying notice to that effect).
- Grant, suspend or cancel the registration.
- Enforce the standards for genetic counselling centre, genetic clinic and genetic laboratory.
- Investigate complaints of breach of provisions of the Act and the Rules.
- Follow up complaints by initiating legal action the to the court.
- Examine all the Form Fs filled in for each ultrasound, giving full details of the reasons for doing the ultrasound and its result.
- Send decoys to medical practitioners under suspicion and raid the premises or inspect the premises and collect the evidence on the spot.
- Make sure that if a sex determination has been carried out it is recorded correctly.
- Take appropriate legal action against the use of any sex selection technique by any person at any place, *suo motu* or brought to its notice and also to initiate independent investigations in such matter.
- Create public awareness against the practice of sex selection or pre-natal determination of sex
- Supervise the implementation of the provisions of the Act and rules.
- Recommend to the CSB and State Boards modifications required in the rules in accordance with changes in technology or social conditions.
- Take action on the recommendations of the Advisory Committee made after investigation of complaint for suspension or cancellation of registration.

Powers of Appropriate Authority:

Moreover the Appropriate Authority has been invested with the following powers:

a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or its rules;

Legal Position on Declining Sex Ratio and Abortion Rights in India



- b) production of any document or material object relating violations;
- c) issuing search warrant for any place suspected to be indulging in sex selection techniques or prenatal sex determination; and
- d) any other matter which may be prescribed.

The Act also provides for the appointment of an Advisory Committee by the Central or the State Government, as the case may be, to aid and advise the Appropriate Authority in the discharge of its functions. The Advisory Committee is to consist of:

- Three medical experts from amongst gynaecologists, obstetricians, paediatricians and medical geneticists;
- One legal expert;
- One officer to represent the information and publicity department of the respective government;
- Three eminent social workers with at least one being a representative of a women's organization.

WHO CAN MAKE A COMPLAINT?

- the Appropriate Authority concerned;
- any officer authorized in this behalf by the Central Government or State Government or the Appropriate Authority;
- If the Appropriate Authority fails to act on the complaint within 15 days, the person who has made the complaint to the Appropriate Authority of the alleged offence and of his intention given 15 days notice to make a complaint in the court, after the lapse of 15 days, that person can directly approach the court;
- Every public spirited person can activate the PNDT law for the violation of the same and he /she can seek the assistance of a lawyer, an NGO and even a group of persons can file a complaint together since "person" includes a social organization.

Once the complaint is made in the Court the public prosecutor will prosecute it there and the complainant need not be present on every date of hearing.

WHAT HAVE BEEN THE BOTTLENECKS TO THE IMPLEMENTATION OF THE PC & PNDT ACT?

Though the PNDT Act is quite explicit and comprehensive, more than a decade after its passage, the sex ratio continues to fall due to failures in its implementation. Let us examine some of the reasons for this failure, all of which are linked with and feed into each-other:

• The persistent son socio-cultural-religious son-preference: Son preference in India has been so long and so deeply entrenched in the Indian ethos and social structures, that it is difficult today to tell if it is the cause or symptom of subordinated status of daughters/ girls in Indian society. Clearly, it requires sustained social and cultural action by government and civil society and cannot be addressed by just legal action.

• The clout of the medical professionals: Son-preference has been around for centuries, but the sex ratio has started dramatically declining due to the misuse of technology. The misuse of technology to support son-preference, is plain and simple, a gross medical malpractice that is impermissible under any legal regime anywhere in the world. In India, it thrives despite legal sanctions because of the sheer clout, social as well as economic, exercised by the medical professionals in this country so much so that no one is ready to see them as criminals. This creates invisible but stout barriers to the implementation of the law against them.

- Attitude amongst medical practitioners and general public: Related to the above, there is a widely prevalent justification either believed or apparently professed by medical practitioners that choosing the sex of the child is part of the personal choice of the family. They are also often heard to proclaim that it is better for the girl child not to be born than for her to suffer discrimination later on in life.
- Financially lucrative practice: Also related to the above two is the fact that medical practitioners conducting PNDT have vested financial interests in continuing the practice; for some of them these form the major portion of their monthly earnings. There is also widespread corruption related to registration of ultrasound clinics and machines for the same reason, which is possible due to the strong nexus between all the vested interests.
- Collaboration between the user and the practitioner and lack of proof: All the people involved in
 the offences under the Act are interested parties. Thus there is no 'complainant'. If a third party
 complains, since the family would be penalised as well as the doctor, it is difficult to find proof that
 a sex selective abortion has been done or that sex determination has been carried out.
- Criminalisation of women: Related to the above point is the fact that the Act has made the woman seeking the PNDT services also criminally liable (unless coercion is proved) and fails to make the medical practitioner wholly and solely liable for indulging in the medical malpractice. This has a dampening effect on the prosecution against the medical practitioners who can and do easily pass the blame on the woman and escape liability by making the woman the scapegoat.
- Lack of punitive action against radiologists and doctors found guilty: Also related to the above two
 points is the fact that even when the suspicion index against the medical practitioner is very high
 or there is proof of violation, hardly any convictions have been made. The representation and
 presence of medical community in various authorities and boards protects its own co-professionals
 at any cost.



HOW CAN IMPLEMENTATION OF PC & PNDT ACT BE STRENGTHENED?

- Address 'supply' side as medical malpractice: Apart from the usual measures to ensure strict implementation of the letter of law, strategically it would help immensely if we narrow down the offenders under the PC/PNDT Act, to only the "supply" side, instead of demand. It is the medical service providers who must be held squarely and solely liable for misusing technology for sheer greed for money, justifying it as being good for women. Any misuse of medical technology is a clearly established medical malpractice and must be recognized as such, without having to make the woman a partner in crime, keeping in mid the complexity of the background to the woman's actions and thinking.
- Maintaining medical records and audit: Further, the medical professionals must no longer be able to get around their duty of maintaining the medical records and submitting them to audits like medical professionals worldwide are doing but which Indian doctors continue to resist.
- Accountability of AAs to be fixed: We must fix the accountability of the Appropriate Authorities set up under the Act, in the sense that we do not just rest with putting their responsibilities on paper but also have the consequences of non-performance of their duties clearly laid down. The civil society stakeholders will then have more meaning to their vigilance role.
- Publicisation of offences with strong social advocacy against son preference: The offences under the Act must be publicized well through all the available effective means, especially in local languages, so that people understand that they are crimes (even when committed by doctors). Alongside, most importantly, there has to be strong social advocacy among women against son-preference, through strong campaigns, awareness raising and information dissemination within the context of gender justice and equality.
- Sensitization of medical professionals: Lastly, we need to lobby also with the medical professionals many among whom may genuinely believe that a declining sex ratio does not mean that fewer women will slowly regain their status in society in future. Finally all stakeholders would need to see that it would be totally to the contrary.



Some notable initiatives towards implementing the PCPNDT Act:

- A determined Appropriate Authority, CMO or DM can most certainly create circumstances whereby the medical community is quickly persuaded to abide by the PNDT Act. The first-ever prison term for sex-selective abortion in India was given to a Haryana-based doctor and his assistant in 2006 when a Faridabad court sentenced Dr Anil Sabhani and his assistant Kartar Singh to two years in prison and a fine of Rs 5,000 each under the Pre-Conception and Pre-Natal Diagnostic Techniques Act 1994 (PC & PNDT Act), for conducting tests to determine the sex of an unborn baby, a practice which is banned in India. The landmark judgment has given a boost to the campaign against sex selection waged by various NGOs. It was Dr BS Dahiya, former Director General of Health Services of Haryana, nailed Dr Sabhani via incriminating evidence in audio and video tapes, in his capacity as district appropriate authority (AA). The AA had raided Dr Sabhani's clinic on October 11, 2002 and lodged a case against him on November 5, the same year. From 2001 to 2004, during Dahiya's tenure, the AA registered 23 cases against doctors conducting sex selection.
- In May 2006 Sahara Television exposed 100 doctors involved in these crimes in Rajasthan and adjacent States. This spurred a major public campaign in Rajasthan. Due to pressure from Women's Groups the State government registered criminal cases against 21 of the doctors involved. So far, seven Doctors have been suspended by the Rajasthan Medical Council. This incident had spurred the State government to convene the first meeting of the State Advisory Board constituted under the PC PNDT Act. It is to be noted that the Advisory Board had never had a meeting before.
- Tactics like the use of trained decoys have helped to provide proof of sex determination and selection. While the government agencies have more commonly used such strategies, the media has also used sting operations to 'catch' practitioners in the act. Even one conviction can alarm doctors in the area sufficiently to desist from such practices. However, if these do not result in action, they lose their impact. Since 2003, DMVM, a Satara-based organisation, has conducted a series of sting operations using decoy patients and has so far managed to nab over 16 doctors for violating the Act in Satara, Thane, Navi Mumbai, Jalgaon, Raigad and Kolhapur districts of Maharashtra. There are over 4,000 registered ultrasound clinics in Maharashtra.
- In a number of districts, which have had success in reversing the decline, the key has been computerization and analysis of Form F. This analysis shows patterns of clinic usage which are indicative- though not evidence by themselves. Once a suspicious pattern is noted, decoys are used to get the evidence. This needs to be supplemented by decoy use to ensure that the



filing of form F is complete, and the sex selection clients are not being excluded from registration.

- Following this success, NGOs have joined hands to collect and analyse 'Form F' in 10 districts of eight states of the country. According to section 17.3 of PC & PNDT Act, every sonologist is required to fill Form F before conducting an ultrasound on a pregnant mother. The form has 19 questions including the reason for conducting the sonography, along with patient detail. Every ultrasound clinic is required to submit Form F to the appropriate state authority by the fifth of every month. The clinics are supposed to keep the record of Form F with them for three years. The NGOs are collecting the forms from the AA of the various districts for a period of three months chosen randomly.
 - The Union Ministry of Health and Family Welfare will help the NGOs by getting permission from the AAs for sharing the Form F data. Some key NGOs involved in the study are Centre for Education into Health and Allied Themes CEHAT (Maharashtra), Centre for Health Education Training and Nutrition Awareness (CHETNA) and Sahiyar Stree Sanghathan (Gujarat), Prayas and IFES in Rajasthan, Sutra (Himachal Pradesh), VHS (Punjab), Samtrita (West Bengal) and Centre for Women's Development (Delhi). The study will be co-ordinated by CEHAT.

The districts chosen for the study are Bhubaneshwar in Orissa, Chittorgarh in Rajasthan, Ahmedabad and Mahasade in Gujarat, Solan in Himachal Pradesh, Hyderabad in Andhra Pradesh, Kolkata in West Bengal, Madurai in Tamil Nadu, South Delhi and South Mumbai.

However, there is a critical balance between state intervention in favour of the girl child and its invasion into the private domain that must always be kept in mind.

Let us consider this pilot plan being tried by the government on improving sex ratios :

The Union Health Ministry and Women and Child Development Ministry proposes to start registering pregnancies in 10 blocks shortly. The project — a first of its type— will be used to prepare a database of pregnancies and keep a track on the number of pregnancies that ultimately result in childbirth. The detailed database thus formed will help in singling out the issues involved in certain pregnancies that do not result in births, and the ministry would then take up the matter with the ministry or department concerned.

The WCD ministry will also implement a new scheme for girl children in these 10 blocks. Under the scheme, the girl child will get a cash transfer of over Rs 7,000 and an insurance cover of Rs one lakh immediately after birth.

Thereafter, the government will pay for her immunisation charges and education expenses till she clears her class X examinations. And after she is 18 years old, the government will give another small amount to make her financially stable.

This plan is a mix of a very close and possibly intrusive monitoring of pregnancies with conditional cash transfers- a carrot and stick approach. Discuss how feasible such monitoring is, how desirable it is, and how replicable this is. Discuss the same three questions with respect to the conditional cash transfers too.

How can civil society contribute to implementing the PNDT act:

- a. By ensuring complete registration of all ultrasound clinics(PNDT clinics). Check the list on the website or display. If the NGO learns of any clinic not on the list report it.
- b. By assisting in or undertaking analysis of form F for suscpicious patterns.
- c. By assisting authorities for decoy action to find out -a) whether all clients are being registered and form F filed and b) whether sex identification is being done.
- d. Bringing to notice of the appropriate authority any advertisement or promotional material.
- e. By assisting in awareness campaigns focused in those groups where the problem is most rampant.
- f. By participating in the implementation mechanisms where invited and by building capacity of those nominated on the committees.
- g. By advocacy and education of the appropriate authorities to ensure that the mechanisms function as intended.

How can the Appropriate authority become more effective:

- a. Put on display- in a website and at the main implementation office, the list of registered PNDT clinics and ask public information to ensure that it is complete.
- b. Strengthen the health management information systems and from it obtain information of sex ratio at birth, by facility and by blocks and use it to identify areas and communities where greater attention is needed. This information should be available on a regular basis and trends should be analysed professionally.
- c. Systematically collect and analyse form F for suspicious patterns of usage.
- d. Use of decoys to gather evidence against those suspected either through form F analysis or due to reports from the public.
- e. Draw up a list of NGOs who are willing to help and involve them wherever possible. They would be useful for technical support and in field support.
- f. Undertake active advocacy within the medical profession taking the help of professional bodies.
- g. Ensure prompt and legally sustainable action on infringements and violations of the Act.

LAW FOR MEDICAL TERMINATION OF PREGNANCIES - MTP ACT, 1971:

Indian government had passed the Medical termination of Pregnancy Act in 1971 to liberalise the law to allow abortions (under certain conditions and circumstances) to address concerns over the large number



of illegal abortions that were occurring in the country in unsafe conditions, endangering lives of the women.

Prior to the enactment of the MTP Act in 1971, the issue of abortion or voluntarily causing miscarriage, was covered under an antiquated colonial legal regime reflected in sections 312-316 of the Indian Penal Code of 1860, under which voluntarily causing miscarriage was an offence punishable with imprisonment of 3-10 years, and both the abortion provider and the woman could be punished for causing the miscarriage, the only exception in the IPC being a termination done in good faith to save the life of the mother.

The provisions of the IPC still exist but the MTP Act exonerates the registered medical practitioner of any offence under that code or any other law for the time being in force, if any pregnancy is terminated by him in accordance with the provisions of the MTP. What the MTP Act did was to expand the indications for which MTPs could be done, without attracting action under the IPC. Here we would be looking at the provisions of the MTP Act along with attempting a short critique from the perspectives of public health as also women's rights.

SALIENT FEATURES³ OF MTP ACT, 1971⁴:

CONDITIONS AND CIRCUMSTANCES FOR LEGAL MEDICAL TERMINATION OF PREGNANCY UNDER THE MTP ACT:

(A) WHO CAN LEGALLY TERMINATE A PREGNANCY?

Only a Registered Medical Practitioner satisfying the following requirements can terminate the pregnancy:

- Possess a recognized medical qualification as defined in the Indian Medical Council Act, 1956
- Have her/his name entered in a state medical register
- Have such experience or training in gynecology and obstetrics as prescribed by the MTP Rules made under the Act:

Experience and training required by a Registered Medical Practitioner

➤ For 1st trimester MTPs:

A practitioner should have assisted a Registered Medical Practitioner in 25 cases of medical termination of pregnancy of which at least five were performed independently in a hospital established or maintained by the government or a training institute approved for this purpose by the government.

➤ For 2nd trimester MTPs:

• A practitioner who holds a postgraduate degree or diploma in Obstetrics and Gynecology, not further experience or training is required. However, for the practitioners who are not qualified Obstetrician/

³ Portions of this section are adapted from "Abortion & Law: Implementers' Guide", GoMP-IPAS, April 2007

⁴ The complete texts of the MTP Act, Regulations and the Rules are available at: http://www.health.nic.in/MTP.htm

Gynaecologist, there must be qualifying experience of six months as House Surgeon in Obstetrics and Gynecology, or at least one year experience in the practice of Obstetrics and Gynecology at any hospital that has all facilities.

However, if termination is performed by a Registered Medical Practitioner in good faith to save a woman's life, it will not be treated as an offence even if it is done by a Registered Medical Practitioner who does not have the legal requirements to perform MTP or at a non-approved site.

(B) WHEN CAN PREGNANCY BE LEGALLY TERMINATED?

A pregnancy can be legally terminated only when a Registered Medical Practitioner is of the opinion formed in good faith (for termination between 12-20 weeks, the opinion must be of two Registered Medical Practitioners) that:

 Continuation of pregnancy is a risk to the life of the pregnant women or it can cause grave injury to her physical or mental health

 Substantial risk that the child, if born, would be seriously handicapped due to physical or mental abnormalities

The pregnancy was caused by rape (presumed to constitute grave injury to mental health)

 Pregnancy caused due to failure of contraceptive in married women or her husband (presumed to constitute grave injury to mental health)

(C) WHERE CAN PREGNANCY BE LEGALLY TERMINATED?

- MTP can be performed only in a hospital established or maintained by the Government
- A place approved by the Government or a District Level Committee constituted by the Government

Process of site approval for private facilities performing MTP:

The MTP Rules cover the following:

- composition of the District Level Committee,
- site approval process and
- experience and training requirement of MTP provider.

District Level Committee (DLC) or approval of place for performing MTP:

The District Level Committee is appointed by the Government and is responsible for approval/ suspension of place for performing MTPs, and is **chaired by the Chief Medical Officer** or District Health Officer and consists of the following:

- 3 to 5 members including Chairperson (Chief Medical Officer or District Health Officer)
- One member must be a Gynecologist/ Surgeon/Anaesthetist
- Other members must be from the local medical profession, non-governmental organization and Panchayati Raj Institution of the district
- At least one member of the Committee should be a woman



The tenure of the Committee is for two calendar years and the tenure of the NGO member cannot be for more than two terms.

Requirements for approval of a place

Rules now segregate sites that offer only first trimester (up to 12 weeks) MTPs and sites that offer MTPs up to 20 weeks.

Places for performing 1st Trimester MTPs:

A place can be approved for terminating pregnancies up to 12 weeks if it has the following facilities:

- Gynecology examination/labor table
- · Resuscitation and sterilization equipment
- Drugs and parenteral fluids
- Back-up facilities for treatment of shock
- Facilities for transportation

Places for performing 2nd Trimester MTPs:

For terminating pregnancies up to 20 weeks the place should also have the following facilities:

- An operation table and instruments for performing abdominal or gynecological surgery
- Anesthetic equipment, resuscitation and sterilization equipments
- Drugs and parenteral fluids for emergency use, notified by Government of India from time to time

Places for performing Medication Abortion (MA)

In case of termination of early pregnancy up to seven weeks using Mifepristone and Misoprostol, the Registered Medical Practitioner, as defined by the MTP Act, can prescribe the drugs at his/her clinic provided he/she has access to a place approved for terminating pregnancy under the MTP Act. The place where MA is prescribed does not need approval. The clinic should display a certificate to this effect from the owner of an approved place.

WHAT ARE THE DUTIES OF CHIEF MEDICAL OFFICERS (CMOS)?

(A) Duties of Chief Medical Officers in approval process:

- The approval for the place can be applied for in Form A and addressed and submitted to the Chief Medical Officer (CMO) of the concerned district.
- The CMO must verify the information provided in the application and inspect the place to satisfy himself that the MTP will be performed there under safe and hygienic conditions. If the CMO is satisfied after verification, enquiry or inspection, he/she will recommend approval of such place to the District Committee (DLC).

 After considering the application and the recommendations of the CMO, the DLC approves the place and issues a certificate of approval in Form B.

• In terms of timeframe, the CMO must inspect the place within 2 months of the receipt of application and certificate of approval must be issued by DLC within next 2 months or if there is any deficiency noted, within 2 months of the efficiency being rectified by the applicant.

(B) Other duties of the Chief Medical Officers:

- Even after granting approval, the CMO must inspect the approved place as often as may be necessary to verify that MTPs are being performed there under safe and hygienic conditions
- If the CMO has any reason to believe that there has been death or injury to any woman user of services at the place or that the termination is not being done under safe and hygienic conditions, he/she can seek any information or seize any article, medicine, admission register or other documents
- If, after inspection, the CMO is satisfied that the facility is not being maintained properly and termination cannot be performed in safe and hygienic conditions, he/she must report this fact to the Committee, upon which the DLC might suspend or cancel the approval after giving the owner an opportunity of being heard.
- The owner whose approval has been suspended or cancelled can apply for a review within 60 days of the order and the Government may confirm, modify or reverse the order
- Also, the owner of the place whose approval has been suspended or cancelled, can apply again for approval after making additions or improvements to the place.
- The CMO must also ensure that he/ she receives the monthly statement of MTP cases in Form II from every head of the hospital/owner of the approved place.

WHAT ARE THE ESSENTIALS OF SAFE AND LEGAL ABORTIONS?

Abortion is safe and legal only when it fulfils the following conditions:

- A Registered Medical Practitioner who is allowed to terminate pregnancy as defined by the MTP Act performs it.
- It is performed at an approved place under the Act.
- Other requirements of the Act like consent, opinion of Registered Medical Practitioner etc. are fulfilled.



Punishable violations under the Act:

- Any person terminating a pregnancy, who is not a Registered Medical Practitioner, can be punished with rigorous imprisonment for a minimum of two years and a maximum of seven years.
- Anyone terminating a pregnancy at a place, which is not approved, can be punished with rigorous imprisonment for a minimum of two years and a maximum of seven years.
- The owner of a non-approved place, performing termination of pregnancy can also be punished with rigorous imprisonment for a minimum of two years and a maximum of seven years.
- If termination is performed by a Registered Medical Practitioner in good faith to save a woman's life, it will not be treated as an offence even if it is done at a non-approved site or by a Registered Medical Practitioner who does not have the legal requirements to proform MTP.

WHAT ARE THE RIGHTS OF A WOMAN UNDER THE MTP ACT, 1971?

The MTP Act lays down only a few rights of the woman user, though they are not absolute and universal, and not couched in a rights language:

- Consent: It is significant that only the woman's consent is required to terminate her pregnancy. (Form C). There is no legal requirement of consent of her partner, though in practice my providers insist that even the adult woman brings her husband along, which is a totally illegal condition. However, in case of minor (less than 18 years) or a "mentally ill" woman, consent of a guardian is required (Form C)
- Confidentiality: Though the MTP Act does not lay down provisions for confidentiality, the MTP Regulations, 2003, notified under the Act do lay down several provisions for ensuring the woman user's confidentiality, which are legal requirements, and may be summarized as follows:

(i) Custody of Forms

- Form C with the consent of the woman and Form I (opinion and certification of termination by provider) must be sealed in an envelope by the provider performing the termination and must be kept in their safe custody until it is sent to the head of the hospital/owner of the approved place or CMO.
- The serial number assigned to the pregnant woman in the admission register and the name(s) of the provider(s) must be noted on each envelope and marked "SECRET".
 Every envelope must be sent immediately after termination of pregnancy to the head of the hospital/ owner of the hospital where pregnancy was terminated to be kept in safe custody.

(ii) Maintenance of Admission Register:

 Every Head of the hospital/owner of the approved place must maintain a register as per Form III for recording the details of the women and keep in secret custody for five years from the end of the calendar year it relates to. This register is a secret document which must not be disclosed to any person except under authority of Law.

• Entries in the Admission Register shall be made serially and a fresh serial started at the beginning of each calendar year. The serial no. will be distinguished by the year, e.g. SN 5/2006; 5/2007. Reference to the woman in other records will be made by the S.No. assigned to her in the Admission Register.

 No entry by name shall be made in any case-sheet, operation theatre register, follow-up card or any other document other than the Admission Register.

LOOKING AHEAD, ON MTP ACT:

The MTP Act ought to move ahead from a physician dependent and physician centered regulation approach to abortion. The law must enable provisioning of access to safe abortion services to all women, on request.

The *rights* around abortion that are well recognized in the international standards to which India is already a party are required to be legally recognized in domestic law.

It is also important to recognize the public health approach to abortion services. The bio-medical interventions cannot be implemented in isolation, without taking into account a host of social factors affecting abortion-related illness and deaths. Firstly, the linkages of abortion related complications with maternal mortality and morbidities are clear, as mentioned in the statement of objects and purposes, yet they are not factored into the substantive body of the law at present. Further, the linkages with several other socio-cultural factors have to be recognized and addressed, like the socio-culturally subordinated status and position of women, especially reflected in extremely poor negotiating powers around their sexual and reproductive lives; poor availability and access to contraception services along with social notions of sexuality and fertility/ infertility that result in unwanted/ forced pregnancies and act as barriers to women accessing safe abortion services; women's lack of access to and control over resources and health services in general; poor sanitation and hygiene leading to wide prevalence of STI/ RTIs among women; continuing resort by women to harmful traditional practices for terminating pregnancies; strong son-preference in the country coupled in some states with continuing coercive and target based population policies/ two-child norm resulting in forced/ repeated abortions; general misconceptions and high rate of illiteracy among women; increased risks of unsafe pregnancy due to women's vulnerability to sexual and other abuses, in and out of marriage and also due to several social, religious and economic customary practices; poverty resulting in inability to afford services; infrastructure and logistical factors like poor communication, roads and transport facilities, and so on. Thus there cannot be only a technical, medicalised



approach to abortion services limited to bio-medical factors alone. The legal response has to be broadened to preventive, community-based approaches around the socio-economic, cultural and political determinants of abortion related morbidities and mortalities.

Also, the widely prevalent morbidities and mortalities due to the reasons of denial of abortion services or their provisioning in unsafe conditions have to be addressed by building awareness and sensitivity on part of the provider as well as the user, but also on part of the communities and especially certain disadvantaged/ vulnerable sections of population that are often inequitably denied the services.

To address the above concerns, the range of services provided for under the act must be broadened to a comprehensive set of services both pre- and post- MTP (Comprehensive Abortion Care or CAC). Also, to ensure accessibility, the provider base needs to be expanded to include mid-level providers and also providers from indigenous systems of medicine, apart from allopathic system, with appropriate training and skills, for various categories of MTP related services.

THE INTER-SECTIONALITY BETWEEN THE LAW AGAINST SEX SELECTION/ DETERMINATION AND THE LAW FOR MEDICAL TERMINATION OF PREGNANCIES:

The main link between the two issues is that the drop in the sex ratio could not have been actually caused unless the sex determination tests being followed by abortion of female foetus (when the test reveals the sex of the foetus as female). This link has led many people, including those working for womens rights to make two kinds of wrong inferences –

- a) that the PC & PNDT Act illegalizes and criminalizes what are termed as 'sex-selective abortion'. This is not true. It illegalizes sex determination, and not the abortion per se.
- b) in case it does not already do that, demanding that it now ought to, and thus the abortion law of India, the MTP Act, must also be amended to stop 'sex-selective' abortions. This could lead to curbs in the access of abortion services, which were in any case have not been very accessible.

In the process, Indian women are not only losing a valuable right to control their own lives, but also abortions are likely to become even more underground and unsafe. A focus on curbing 'sex selective abortions' in contrast to a focus on curbing sex determination, is unlikely to be an effective strategy to even address the issue of adverse sex ratio.

The importance of recognizing and preserving right to abortion

Excerpt from: "From the Abnormal to the Normal" by Indira Jaising et al (Lawyers' Collective)

"At the outset it has to be clarified that we do not view the problem of sex selective abortions as a pro-life or pro-choice issue. In the context of patriarchy and women's inequality, the right to abortion needs to be considered as a historical necessity. Disproportionate burdens are placed on a woman at the time of child birth and child rearing. The biological burdens during pregnancy are evident. In

addition, women are constrained by socially defined roles of being better care gives. This severely impinges on their freedom and autonomy. This necessitates the recognition of the right to abortion.

Other reasons that necessitate the recognition of the right to abortion are:

- Women often do not control the conditions under which they become pregnant. Even today marital rape is not recognized as a punishable offence in India.
- Contraceptive failures, as well as the non-availability of effective and safe contraceptives play an important role in a woman's state of pregnancy.
- Poverty and economic dependency are factors that impact adversely on women's physical integrity and sexual self determination.
- Lack of support structures such as the provision of day care are also important considerations for a woman to decide on continuing with a pregnancy. (Mackninon 100 Yale Rev 128)

Another important reason is that in the context of the patrilineal structure of society, where the identity of an individual is derived from the father, it is essential for women, pregnant outside social sanction (such as widows, or unmarried women), to have unimpeded access to abortion services. Therefore, the final decision on whether to continue with a pregnancy or not, has to vest with the women."

Keeping this distinction between sex-selective abortion and sex determination in mind some points are being flagged here:5

- First of all, we need to be clear that the PC & PNDT Act does not make sex-selective abortions illegal, it only makes sex-determination or sex-selection illegal. This is not a careless omission, but a thoughtful and deliberate silence since this law was made with active civil society participation which had an understanding that the two issues should not be confounded. This is one reason why the entire process of PNDT act implementation is focussed on the point of sex determination and not on the place of abortion.
- It is difficult, indeed impossible, to determine which abortion is "sex-selective" clearly every abortion of female foetus is not sex-selective, only those abortions of female foetuses that are carried out due to the sex of the foetus is sex-selective. But how does one practically prove this at the point of abortion?
- Related to the above reason, the direct impact of banning or illegalising 'sex-selective abortion'

⁵ Portions of this section are adapted from a paper by Shruti Pandey under consideration for publication.



would be the beginning of the end of abortion rights. Indeed, in some states (Maharashtra, Tamil Nadu, Pondicherry) 2nd trimesters are no longer being provided in government facilities due to the scare caused on the issue of sex ratio and the providers fearing their prosecution.

• It is clear from experiences the world over that making abortions illegal does not stop abortions, it only pushes abortions further underground. The number of unsafe abortions carried out by untrained persons would increase and access to abortions would become even more difficult. The declining sex ratio would continue to decline further through illegal sex-selective abortions. Most definitely, neither of the two causes would be served.

Ironically, the demand to link up the two issues has come, in various shades, from within the sections of Indian women's rights movement itself, who fail to make this distinction. They assume that these two terms are synonymous, failing to see the danger in using the term sex selective abortion instead of sex determination. Many of them continue to use the language of female "foeticide" (in Hindi *bhroon "hatya"*) or "killing" of female foetuses, to address this issue, thus concentrating totally on sex-selective abortions. There is evidence that messages related to the illegality of sex selective abortion conveniently or inadvertently merge into illegality of abortion. The language of sex selective abortion threatens women's reproductive rights as it threatens access to abortion.

- We need to look at sex-determination issue from a broader women's rights/ gender discrimination perspective and within the abortion rights discourse that the woman's right to abort includes her right not to abort, or more clearly put, her right not to be forced to abort giving the woman the 'choice' of continuing or discontinuing the pregnancy. Within this perspective, while sex determination/ selection is definitely a gender discrimination issue, it has to be seen not as discrimination against unborn female foetus, but as discrimination against the woman/ mother as she is directly (by husband, in-laws) or indirectly (under social expectations and pressures) being forced to abort, many times repeatedly, which also takes a heavy toll on her health, apart from violating her lesser recognized right to self-determination.
- Directly, this means that women cannot be penalized under the PC/PNDT Act in any circumstances. For the purposes of looking at intersection between sex-selection and abortion rights, this would mean that unless the element of force or coercion is made out by the woman herself, a 'sex-selective abortion' is totally legal on part of the woman. This in turn would mean that it must remain in the hands of the woman to complain, and it would not lie with the society to screen and track pregnancies and abortions, without any regard for women's rights of privacy, confidentiality, apart from autonomy, as is being done in some parts of the country already, for instance, in Nawabshahar district in Punjab where some time back abortions were being 'mourned' with white bands outside the houses of the women, ostensibly to stop decline in juvenile sexratio; or more recently some state government's move to stop second trimester abortions, and

inclination of Union Ministry of Women & Child Development to track/ monitor all pregnancies and abortions.

- While we must work out, on the most urgent basis, the modalities for more effective checks and measures to stop pre-birth sex-selection and sex-determination, and strictly implement the PC&PNDT Act, it is extremely important that we remain alert to the politics and very real dangers of pitting the unborn female foetus' right to life against the mother's right to her body. Today with the increasing sway of rightist, retrogressive forces, there are many vested interests which are confounding the two, taking advantage of the confusion and pitting them against each-other. These forces are clearly beginning to articulate a language along these lines and openly asking now for even the limited abortion rights of Indian women to be taken away under the pretext of checking the decline in sex-ratio. It is also important to recognize the increasing attack on women's right to abort in many parts of the world today, which forms a context to this growing trend in India too. Let's not fall into this dangerous trap and use any language that condemns "killing" of unborn girl-child or postulates female foetus' right to be born or her right to life.
- It is also important to understand that in any case, even practically speaking, curtailing a woman's right to abortion is a far more difficult way to address decline in sex-ratio since it would involve monitoring all the pregnancies and checking on the reasons for abortion, which as explained above is well nigh impossible. To check the misuse of technology in the hands of doctors reduces the monitoring to be carried out to a much smaller scale. Also, if we choose the latter, we do not have to resort to the former. The latter, i.e., the misuse of medical technology, will have to be monitored in any case as that will still remain a gross medical malpractice which must be stopped.
- Therefore, the only way forward is stricter implementation of the PC/PNDT Act on the front of sex
 determination and even within that to focus legal action only on the supply side by penalising the
 providers indulging in misuse of medical technology and thus committing medical malpractice,
 while stepping up the role of social movements and processes against the problems of son
 preference.



Review Questions:

- 1. What are the offences/ crimes under the PC & PNDT Act?
- 2. What are the legitimate uses of the technologies for pre conception and pre natal diagnosis and sex-selection?
- 3. What are the meanings of terms 'pre natal diagnostic techniques' (PNDT) and 'sex-selection'?
- 4. Whereas under the PNDT act sex determination is illegal, sex selective abortion is not. What is the importance of making this distinction?
- 5. What are the roles and responsibilities of district medical officers under the PC & PNDT Act?
- 6. What are the reasons for weak implementation of the PC & PNDT Act and how can the implementation be strengthened?
- 7. Who can legally terminate a pregnancy under the MTP Act?
- 8. When and where can a pregnancy be terminated under the MTP Act?
- 9. What are the duties of the Chief Medical Officers under the MTP Act?
- 10. What are the rights of women under the MTP Act? Do they have rights under this act is it a trick question?

Application Question:

- 1. What are the ways in which the PC & PNDT Act can be more successfully implemented? Do you think that the issue cannot be addressed effectively through law at all, or through law alone, and if you agree, what are the ways to address it effectively?
- 2. Discuss the changes needed in the MTP act to make it centred around womens rights. What are the changes occurring in access to MTP- both in practice and in legal perception consequent to the concerns about declining sex ratio in your district/state. Discuss

Project Work:

- 1. Carry out an assessment of the implementation of the PNDT Act in your district: What is the sex ratio? What mechanisms are in place to measure these and at what levels of disggregation? How many ultrasound clinics exist? How do we know whether the registration is complete? What is the process for analysing Form F returns?
- 2. Do a case study of one or more clinics that were booked under this act and the process leading upto prosecution and conviction.





Lesson EIGHT

References, Technical Resources and Further Readings



Lesson 1: Understanding Concept and Contours of 'Right to Health'

Abhichandani, R.K: Health as Human Right-Role of courts in realization of the Right, http://www.citehr.com/21807-health-human-right-role-courts-realisation.html (accessed on May 15, 2009)

Balakrishnan, K.G, "Address at the National seminar on the 'Human right to health" *Madhya Pradesh State Human Rights Commission*, Bhopal: September 14, 2008 http://www.supremecourtofindia.nic.in/speeches/speeches_2008/Right_to_Health_-_Bhopal_14-9-08.pdf

Sharma Kalpana, "Viewing health as an inalienable right", India Together: October 7: 2005 http://www.indiatogether.org/2005/oct/ksh-health.htm

Shukla, Abhay, "A compiled review of the rights approach to health and health care", *Beyond the Circle*, 2007

The Right to Health as Established in International Law, http://www.lawyerscollective.org/un/right

United Nations High Commissioner for Human Rights. "What is a Rights-Based Approach to Development?" www.unhchr.ch/development/approaches-04.html

United Nations Population Fund (UNFPA). "The Human Rights-Based Approach" www.unfpa.org/rights/approaches.html

Lesson 2: Legal recognition of health rights: International, Constitutional, and Statutory Health Rights and Obligations

International treaties

CEDAW Convention on the Elimination of All Forms of Discrimination against Women, http://www.un.org/womenwatch/daw/cedaw/index

CEDAW General Recommendations (See especially Recommendation 25 on health and 19 on violence against women),http://www.un.org/womenwatch/daw/cedaw/recomm.htm

CEDAW "The Optional Protocol", http://www.un.org/womenwatch/daw/cedaw/protocol/text.htm

CERD "International Convention on the Elimination of All Forms of Racial Discrimination", http://www.unhchr.ch/html/menu3/b/d_icerd.htm



CMC. "Convention on the Protection of the Rights of All Migrant Workers", http://www.unhchr.ch/html/menu3/b/m_mwctoc.htmml

CRC "Convention on the Rights of the Child", http://www.unhchr.ch/html/menu3/b/k2crc.html

ICESCR "General Comments (See especially Comment 14 on health and 16 on equal rights for women and men)", http://www.ohchr.org/english/bodies/cescr/comments.htm

ICESCR "International Covenant on Economic, Social and Cultural Rights", http://www.ohchr.org/english/law/cescr http://66.36.242.93/treaties/cescr.php

UDHR "Universal Declaration of Human Rights", http://www.unhchr.ch/udhr/

Regional treaties and organizations: Africa

African Charter on Human and Peoples' Rights (1981), http://www1.umn.edu/humanrts/instree/z1afchar.htm

African Commission on Human Rights, http://www.achpr.org/english/_info/index_women_en.html

African Union, http://www.africaunion/org/home/Welcome.html

Council of Europe, http://www.coe.int/t/e/Human_Rights/

EU and Gender Equality, http://europa.eu.int/comm/employment_social/gender_equality/index_en.html

EU and Health, http://europa.eu.int/comm/health/ph_overview_en.html

European Convention on Human Rights (1950), http://www.hri.org/docs/ECHR50.html

European Court of Human Rights, http://www.echr.coe.int/echr

European Social Charter (1961), http://www1.umn.edu/humanrts/euro/z31escch.html

Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, http://www.achpr.org/english/_info/women_en.html

Regional treaties and organizations: Europe

OSCE, http://www.osce.org/odihr/13371.html

Regional treaties and organizations: The Americas

American Convention on Human Rights (1969), http://www.oas.org/juridico/english/Treaties/b-32.htm

Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1988), http://www.oas.org/juridico/english/Treaties/a-53.htm

Consensus documents Beijing plus 5 and Beijing Platform for Action, http://www.un.org/womenwatch/daw/followup/beijing+5.html

Declaration of Alma Ata (1978), http://www.phmovement.org/charter/almaata.html

Declaration of Commitment on HIV/AIDS, 'Global Crisis-Global Action' (2001), http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html

Declaration on the Elimination of Violence against Women (1993), http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/A.RES.48.104.En?Opendocument

Declaration on the Right to Development (Vienna Declaration and Programme of Action) (1993), http://www.hri.ca/vien-na+5/vdpa.html

Declaration on the Rights of Disabled Persons (1975), http://www.unhchr.ch/html/menu3/b/72.html

ICPD Programme of Action (Cairo Programme of Action) Report of the International Conference on Population and Development (1994), http://www.iisd.ca/linkages/Cairo/program/p00000.html

Inter-American Commission, http://www.cidh.org/basic.eng.html

Inter-American Convention on the Prevention, Punishment and Eradication of Violence Against Women, 'Convention of Belem do Para' (1994),

http://www.oas.org/cim/English/Convention%20Violence%20Against%20Women.htm

Inter-Amèrican Court, http://www.corteidh.or.cr/index_ing.html

Organization of American States,

http://www.oos.org/main/main.osp2cl.ong-E8cl.ink _http://www.oos.org/main/main.osp2cl.ong-E8cl.ink _http://www.oos.org/main.osp2cl.ong-E8cl.ink _http://www.o

http://www.oas.org/main/main.asp?sLang=E&sLink =http://www.oas.org/key_issues/eng

Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, Maastricht, January (1997), http://www1.umn.edu/humanrts/instree/Maastrichtguidelines_.html



Millennium Declaration (MDGs) (2000), http://www.developmentgoals.org

People's Charter for Health.

http://www.phmovement.org/pdf/charter/phm-pch-english.pdf

Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (1991), http://www.unhchr.ch/html/menu3/b/68.html

Lesson 3: Professionals Regulation of Health Care Services & Providers

AICTE Act 1987

Baldwin R and M Cave (1999). *Understanding regulation: Theory, strategy and practice. Oxford University Press,* ____

Dentists Act, 1948

Enquiry driven strategies for innovation in medical education in India. Curriculum Reforms -1995.

Harding, April and Alexander S. Prekar (Eds.) (2003). *Private Participation in Health Services* (World Bank).

Indian Medical Council Act, 1956

Ministry of Health and Family Welfare (____), Task force on medical education for the NRHM.

NIHFW (1992), Status study of training in MCH &FW in medical colleges of India.

Peters, David H. and V.R. Muraleedhara (2008). "Regulating India's health services: To what end? What future?" Social Science Medicine, May 66(10):2133-44. (Epub. March 4, 2008)

Report of the National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare. 2005. P 55,56

Shridhar, Sharma (1990). Medical Education in India. In: Medical Education in South East Asia region (WHO-SEARO).

Suresh, P (__). "Dichotomy in the Regulation of Pharmacy Education in India", *Health Administrato*, Vol: XIX Number 1: 92-98

The Homeopathy Central Council Act 1973

The Indian Nursing Council Act, 1947

The Indian Medicine Central Council Act 1970

The Pharmacy Act, 1948

Varadappan Committee (1989), Report of the High power Committee on Nursing and Nursing Profession, Ministry of Health and Family Welfare, New Delhi.

(1992) 1 CPR 820 No.DE-130-2007/A7231 dated 8th Nov. 2007

(1996) 4 SCC 332.

Lesson 4: Right to Information

Kumar, Anu (1999). "Right to Information — Background and Perspective". Infochange India. http://www.infochangeindia.org/Righttinfolbp.jsp

Right to Information Act, 2005. *Ministry of Personnel, Public Grievances and Pensions*. (2005) http://persmin.nic.in/RTI/WelcomeRTI.htm.

Right to Information Act, 2005. "Obligations and Responsibilities". *Government of India*. http://www.rti.gov.in/rti_slides.

State of U.P. vs. Raj Narain, AIR 1975 SC 865 http://judis.nic.in/supremecourt/qrydisp.asp?tfnm=6074

Tamil Nadu Right to Information Act No. 24 of 1997. Government of Tamil Nadu 1998-05-06. http://www.tn.gov.in/acts-rules/right2info.htm

The Official Secrets Act, 1923. IndiaLawInfo.com. 1923-04-02. http://www.indialawinfo.com/bareacts/OSA.html.

Online Portal for Right to Information in India,

World Report: Libraries and Intellectual Freedom (India). *International Federation of Library Association and Institutions*. (1999) http://www.ifla.org/faife/report/india.htm.



http://www.rtiindia.org/http://www.nabble.com/CHRI%27s-submission-with-regard-to-section-7%283%29-of-the-RTI-Act-to-the-CIC-p20847692.html

http://www.nabble.com/Section-7%283%29—filings-to-CIC-td20827644.html

Lesson 5: Food Safety in the District

Maneka Gandhi v. Union of India AIR 1978 SC 597

Safety and Standards Act, 2006

The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act, 1992

The Prevention Food Adulteration Act, 1954

World Health Organization (2002). WHO global strategy for food safety: safer food for better health.

http://www.who.int/nutrition/publications/code_english.pdf

http://www.who.int/nutrition/topics/wha_nutrition/en/index.html

Lesson 6: The Control of Drugs at the district level.

Aggarwal, Aradhna (2004) Strategic approach to Strengthening the International Competitiveness in Knowledge based Industries: The Indian Pharmaeutical Industry. RIS Discussion papers. 80/2004.

CDSCO Interim Report. Strengthening Central Drug Regulatory Agency. http://cdsco.nic.in/html/annex5.htm

Current Science. Vol. 84, No.11, June 2003. Pg 1395

Drugs and Cosmetics Act, 1940

Drugs and Cosmetics Rules, 1945

Drugs (Control) Act, 1950

Drugs (Price Control) Order, 1955

........

Malik, Vijay (2007). Law relating to Drugs & Cosmetics. Eastern Book Company. (19th Edition) pg. A-65.

Pharmaceutical Policy, 2002. http://chemicals.nic.in/pharma4.htm

S, Ratanwijitrasin, and Wondermagegnelu E.(2002). Effective drug regulation: a multi country study, (WHO)

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955

The Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955

The Essential Commodities Act, 1955

The Infant Milk Substitutes, Feeding Bottles And Infant Foods (Regulation Of Production, Supply & Distribution) Act, 1992

The Narcotic Drugs and Psychotropic Substances Act, 1985

WHO Policy perspectives on Medicines (2003), Effective Medicines Regulation: ensuring safety, efficacy and quality, Paper 7.

WHO Policy perspectives on Medicines (2004), *Pharmacovigilance: ensuring the safe use of medicines*, Paper 9.

World Health Organization (2004) *The World Medicine Situation, Rational use of Medicines*, chapter 8, pg. 75.

WHO (2004), The World Medicine Situation, Medicines Regulation, chapter 9, Pg. 93.

WHO Certification Scheme on the quality of Pharmaceutical Products moving in International Commerce. 1995. http://whqlibdoc.who.int/hq/1994/WHO_DAP_94.21.pdf

Lesson 7: Legal Position On Declining Sex Ratio And Abortion Rights In India

Kumar, Shalini. Medical Abortion in Purview of MTP Act, India (1971) presented on Consortium on National Consensus for Medical Abortion in India http://www.aiims.edu/aiims/events/Gynaewebsite/ma_finalsite/report/1_3_8./html

Mittal, Suneeta. Introductory address: Consortium on National Consensus for Medical Abortion in India http://www.aiims.edu/aiims/events/Gynaewebsite/ma_finalsite/introduction.html



lyengar, Sharad. Current status of abortion in India: Advances in Methods of Emergency Contraception presented on Consortium on National Consensus for Medical Abortion in India http://www.aiims.ac.in/aiims/events/Gynaewebsite/ma_finalsite/report/1_1_1.html

Shiva, Mira. Client Needs and Perspectives presented on Consortium on National Consensus for Medical Abortion in India http://www.aiims.edu/aiims/events/Gynaewebsite/ma_finalsite/report/1_3_6.html

Medical Termination of Pregnancy Act 1971, http://www.medindia.net/Indian_Health_Act/the-medical-termination-of-pregnancy-act-1971-introduction.htm

Medical Termination of Pregnancy Amendment Act, 2002 http://www.medindia.net/Indian_Health_Act/medical-termination-of-pregnancy-amendment-act-2002-introduction.htm

Notification on Medical Termination of Pregnancy (Amendment) Act http://www.medindia.net/Indian_Health_Act/notification-on-medical-termination-of-pregnancy-act.htm

Medical Termination of Pregnancy Regulations, 2003 http://www.medindia.net/Indian_Health_Act/Medical-Termination-of-Pregnancy-Regulations-2003-Introduction.htm

Medical Termination of Pregnancy Rules, 2003 http://www.medindia.net/Indian_Health_Act/medical-termination-of-pregnancy-rules-2003-introduction.htm

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